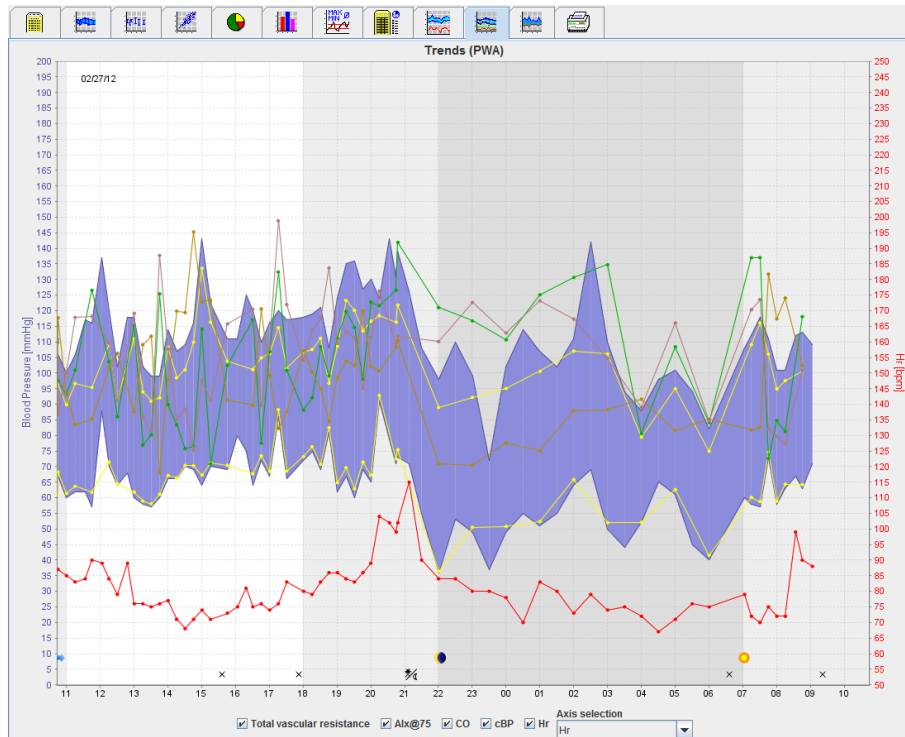


Hypertension Management Software (HMS) 5.0



Directions for Use – PWA-License

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WelchAllyn®
Advancing Frontline Care™

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5 - Symbols

Symbols

The following signal words, symbols and pictographs are used in this direction for use to indicate important information:

Attention	The attention statement marks possible material damage. Non-adherence may lead to damage to the device or its accessories	Note	The note statement marks further information on the HMS
Tip	The tip statement marks a useful tip for example a short key		Consult Directions for Use, Electronic version available at Welchallyn.com , or Hard copy DFU available from Welch Allyn within 7 days.
	INTERNAL REFERENCE Marks references within the document to further information		EXTERNAL REFERENCE Marks references to external documents containing further optional information
	Meets essential requirements of European Medical Device Directive 93/42/EEC		Manufacturer

Introduction

Preliminary note

The Hypertension Management Software (**HMS**) serves to analyze the measurements taken by the blood pressure monitor ABPM 7100 from Welch Allyn.

With the help of the **HMS**, measurement results can be transferred out for analyzes via a USB interface cable or via Bluetooth®.

Measurement values can be displayed in various diagrams and other display formats, then processed further or printed out.

The upgrade to the **PWA License** provides you with the additional option of a pulse wave analysis (**PWA**).

About this directions for use

This direction for use provides you with extensive information on the individual options of analyzing the measurement values from your ABPM 7100.

Safety-relevant information

Safety-relevant information is contained in the directions for use of the ABPM 7100 Ambulatory Blood Pressure Monitor.

Intended use

The Hypertension Management Software is used in combination with the ABPM 7100 for the presentation and analyzes of blood pressure measurements.

The blood pressure curve of the ascending aorta is derived and a series of central arterial parameters are displayed. It is used in those patients where information related to the ascending aortic blood pressure is desired but in the opinion of the physician, the risk of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.



For further information on your ABPM 7100 please refer to the directions for use of the ABPM 7100.

6 - Working with HMS

Description of the HMS

The ABPM 7100 measures blood pressure and stores the measurement. Upon completion of the measurements, the stored measurements can be transferred to your computer, where measurements can be analyzed with the HMS according to your convenience.

The patient file contains data such as:

- Patient ID (mandatory input)
- Name (mandatory input)
- Contact information (address, telephone number, emergency contacts etc.)
- Personal data (age, gender etc.)
- Medication, Medical history, Blood pressure limits

The **HMS** offers you various analysis options. Results can be displayed on the computer screen or printed out:

- Display all individual measurements
- Statistical analysis with mean blood pressure values for the entire day, daytime and nighttime, first hour upon initial measurement, as well as mean hourly values
- Extreme values (maximum, minimum)
- Frequency percentage of measurement values above a specified limit value
- Calculation of daytime / nocturnal decrease
- Deviation from standards (variability)

Graphical analyzes:

- Envelope curve of mean hourly values
- Correlation
- Pie chart of exceeded limits in percent
- Bar chart of measurements
- Curve of changes in blood pressure
- Curve of measurement values
- Histogram of blood pressure distribution
- Curve comparison for treatment optimization

In this way, the course of and fluctuations in blood pressure over the day and night can be quickly and easily visualized. Medication can then be adjusted base on the account of these changes.

Working with HMS

Note Basic knowledge and experience in the Windows®, Mac OS X® or Linux® Operating System is required to use the **HMS**.

The **HMS** is used to administrate and analyze the measured blood pressure measurement data. These measurement values are then assigned to the patient. Each patient is not limited to one measurement series. Each measurement series consists of numerous individual values.

In general the following steps are run through:

- Before measurement: Preparing the measurement
 1. Start the **HMS**.
 2. Select existing patient or create new patient.
 3. Pair the ABPM 7100 to the **HMS**.
 4. Prepare the ABPM 7100 for measurement.
 5. Exit the **HMS**.

7 - Installing the software

- After measurement: Process measurement data
 1. Start the **HMS**.
 2. Pair the ABPM 7100 to the **HMS**.
 3. Transfer the measurement results from the ABPM 7100.
 4. Analyze the measurement results.
 5. Exit the **HMS**.

Installing the software

The **HMS** is able to communicate with the ABPM 7100 via the following connections:

- USB interface cable
- Bluetooth® USB adapter

Note Please insert only the Bluetooth® USB adapter or USB interface cable into the computer after the **HMS** has been installed or when you are prompted to do so.

Provisions for “Cyber Security”

Attention

For provisions of Cyber Security, the following should be observed for the safety of the HMS software

- Do not activate a guest account on the computer.
- Use the database export function for regular backups. The HMS does not provide automatic backups.
- Regularly update your operating system, firewall and antivirus software.
- Do not use Operating Systems for which support has been discontinued.
- Ensure that only authorized personnel have access to your computer.

System requirements

1. Computer
 - 1 GHz
 - 512 MB RAM
 - 100 MB Hard Disk Storage
 - 1024 x 768 Pixels
 - Two spare USB Ports
2. Operating System
 - Windows® Vista, Windows® 7, Windows® 8, Windows® 8.1 (32-bit & 64-bit)
 - Macintosh® OS X 10.7.5 and above (64-bit)
 - Linux® Ubuntu 14.04 and above (64-bit)
3. Software
 - Java-Runtime-Environment (JRE is contained on the installation CD)
4. Bluetooth®
 - Bluetooth® USB adapter
 - Bluetooth® 2.0
 - USB version 1.1 and above
 - BlueSoleil driver or software must not be installed

8 - Installing the software

Installation for Windows®



The directions for use are located in the **docs** folder on the installation CD. Available documents are clearly displayed via **index.htm**.

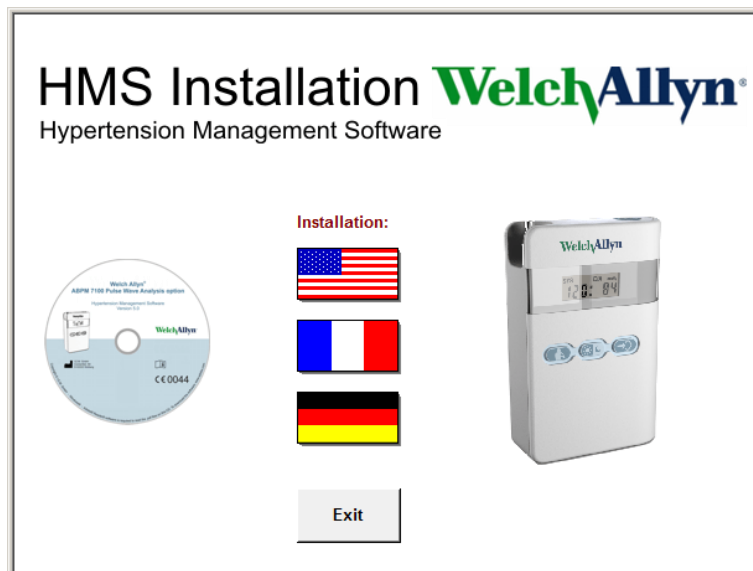
Procedure:

The individual steps are explained in more detail below:

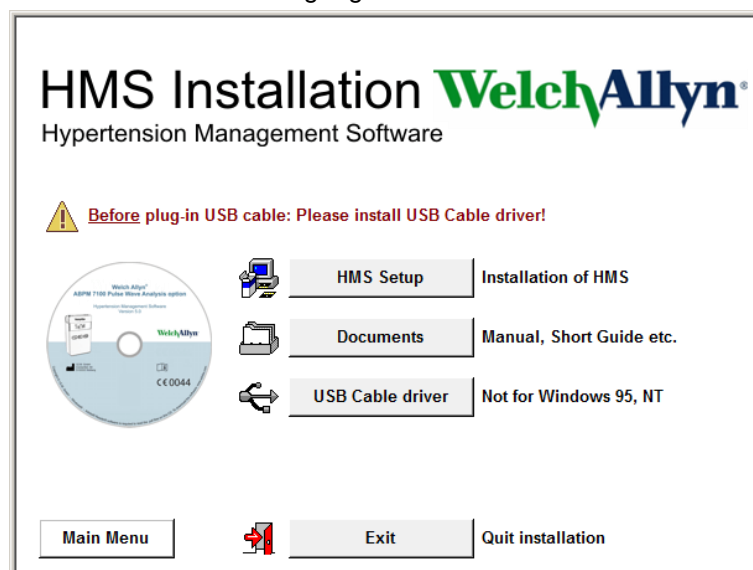
- A. Installing the **HMS** from CD.
- B. If required install drivers from the CD in the following sequence:
 1. Bluetooth® driver
 2. USB driver
- C. Insert the USB interface cable and/or the Bluetooth® adapter into the computer.

Installing the HMS from CD

1. Insert the CD into the CD drive.
2. The **HMS** installation should start automatically. If not, please perform the following steps:
 - I. Open the CD drive in Windows® Explorer.
 - II. Click on the file **CD_Start.exe** to start the installation.



3. Select the installation language. This launches the installation menu.



9 - Installing the software

- Click on **HMS Setup**. The installation wizard appears.



- Select a language and click on **OK**.



- Follow the instructions on the screen.



Installation for Macintosh® OS X 10.7.5 and above

Procedure:

- Installing the application from CD ROM.
- Insert the USB adapter and/or the Bluetooth® adapter into the computer.

Installing the application from CD ROM

- Place the provided CD into your CD ROM drive.
The Desktop will display the CD symbol for **HMS**.
- Double-click on this CD symbol for **HMS**. CD-ROM will open.
- Open the directory **Mac_10-7-5**.
- Move the file **HMS.app** to your program directory.

10 - Installing the software

Installation for Linux®

Procedure:

- A. Installing the application from CD ROM.
- B. Insert the USB adapter and/or the Bluetooth® adapter into the computer.

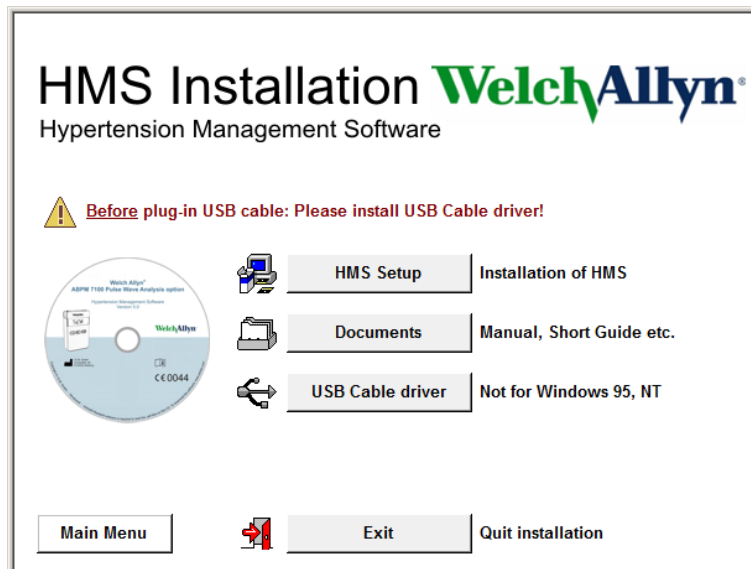
Installing the application from CD ROM

1. Log on as system administrator (root).
2. Place the provided CD into your CD ROM drive.
3. Open the directory **Linux®** on the CD.
4. Copy the folder **HMS** into the Home Directory.
5. Set the file **HMS** as executable in the Home Directory.
6. Create a desktop shortcut to the file **HMS**.

Installing the Bluetooth® driver

No driver is required for the Bluetooth® USB adapter DIGITUS (applicable from Windows® XP SP2 and above).

Installing the USB driver




1. In the installation menu, click **USB Cable Driver**.
2. Follow the instructions displayed on the screen.

11 - Starting and exiting the HMS

Starting and exiting the HMS


Starting the HMS



Double-click the  icon on the computer desktop to start the **HMS**. Information on the loading progress (e.g. program version, progress bar) is displayed.

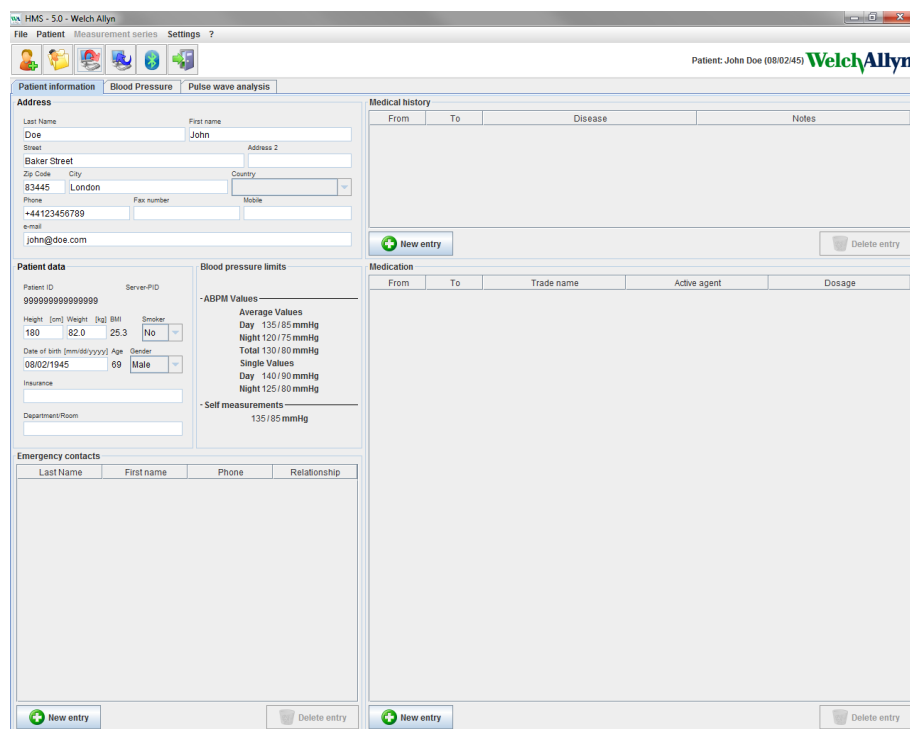
Exiting the HMS



Click the  icon on the application window top toolbar. If any data have been previously changed, the **HMS** will prompt the user if those changes should be saved. Information on the quitting progress is displayed.

Structure of the HMS application window

All functions can be accessed from the application window. Depending on function, additional windows may appear.



The screenshot shows the HMS application window with the following structure:

- Menu Bar:** File, Patient, Measurement series, Settings, ?
- Toolbar:** Contains icons for Patient, Measurement series, and Settings.
- Tabbed Interface:** The main window has three tabs: Patient information, Blood Pressure, and Pulse wave analysis. The Patient information tab is currently active.
- Patient information Tab:**
 - Address:** Last Name (Doe), First name (John), Street (Baker Street), Zip Code (83445), City (London), Country (dropdown), Phone (+44123456789), Fax number, Mobile, e-mail (john@doe.com).
 - Patient data:** Patient ID (9999999999999999), Server PID, Height (cm) (180), Weight (kg) (82.0), BMI (25.3), Smoker (No), Date of birth (mm/dd/yyyy) (08/02/1945), Age (68), Gender (Male), Insurance, Department/Room.
 - Blood pressure limits:** ABPM Values (Average Values: Day 135/85 mmHg, Night 120/75 mmHg, Total 130/80 mmHg; Single Values: Day 140/90 mmHg, Night 125/80 mmHg), Self measurements (135/85 mmHg).
 - Emergency contacts:** Table with columns: Last Name, First name, Phone, Relationship.
- Medical history Tab:** Table with columns: From, To, Disease, Notes. Includes a "New entry" button and a "Delete entry" button.
- Medication Tab:** Table with columns: From, To, Trade name, Active agent, Dosage. Includes a "New entry" button and a "Delete entry" button.

Functions can be called up from the menu bar at the top of the window. The toolbar below the menu bar contains buttons (icons) for the individual processing steps. The main working area contains three tabs:

1. **Patient information**
2. **Blood Pressure**
3. **Pulse wave analysis**

Menu bar

The menu bar is located at the top of the application window.

File Patient Measurement series Settings ?

12 - Structure of the HMS application window

Below shows the functions summary for each item:

File menu

Menu item	Function
Patient list	Display a list with previously created patients.
New patient	Create a new patient.
Import	Import patient data.
Back up data	Database back-up and recovery. (Attention: During recovery, the current database is replaced by the backed up database - risk of possible data loss)
Audit trail	Record all changes to patient data.
Quit program	Exits HMS .

Patient menu

Menu item	Function
Delete	Delete currently processed patients including all measurement data.
Export	Manually export a patient's data.
Change ID	Change the patient number of the currently processed patient.
Discard changes	Reverse changes made to a currently opened patient file.

Measurement Series menu

Menu item	Function
Export (Excel)	Save the currently selected measurement series to an Excel file.
Export (XML)	Save the currently selected measurement series to an XML file.
Export (GDT)	Save the currently selected measurement series to a GDT file.
Delete	Delete the currently selected measurement series.

Settings menu

Menu item	Function
Database	Configure the database.
Language	Specify the language for the program.
Port settings	Specify the port to the measurement device.
Blood pressure limits	Specify limit values for analysis.
Analysis	Specify the settings for the analysis.
Colors	Specify colors for curves and diagram backgrounds.
Format	Specify calculation, display and Bluetooth [®] procedures.
PWA/CBP Activation	Activate PWA Measurement (PWA).
GDT settings	Specify file and directory settings for GDT import / export.

About menu

Menu item	Function
	Display information on the HMS version.

13 - Structure of the HMS application window







Toolbar

The toolbar is located below the menu bar at the top of the application window. It contains buttons (icons) used to call up important functions quickly. The current patient's name and date of birth are displayed on the right.



Patient: John Doe (08/02/45) **WelchAllyn**

Tip If you use the mouse to hover over a symbol, a brief tooltip will appear.

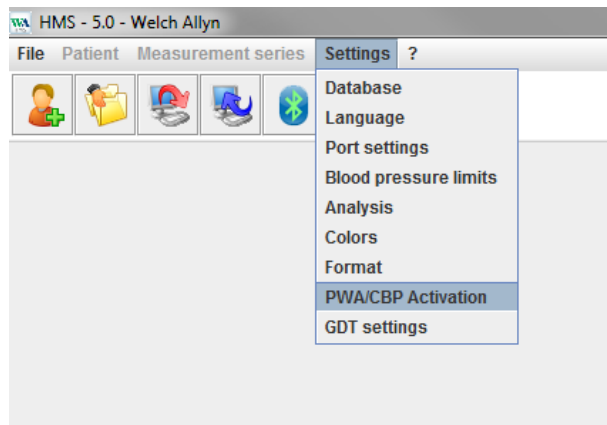
Symbol	Meaning	Function
	New patient	Create a new patient.
	Patient List	Display a list with previously created patients.
	Prepare device	Prepare the ABPM 7100 for the next measurement.
	Upload device	Transfer out measurement values from the ABPM 7100.
	Bluetooth®	red: Bluetooth® not active. green: Bluetooth® active.
	Quit program	Exits HMS .

Note You can also access some of these functions via the menu bar.

Activating Pulse Wave Analysis (PWA)

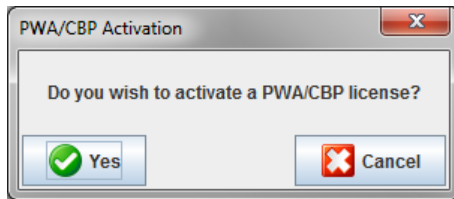
Apart from the 24-hour blood pressure measurement, the ABPM 7100 also has an integrated pulse wave analysis function (PWA). This function can only be unlocked after a device upgrade with a 16 digit license key that is unique to the ABPM 7100 device serial number. Please consult Welch Allyn on device upgrading.

1. Start the **HMS**.
2. In the **Settings** menu, click **PWA/CBP Activation**.

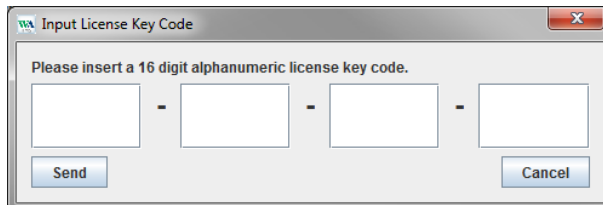


14 - First steps with the sample patient

3. Click **Yes**.



4. The **HMS** will then prompt the user to enter the 16 digit license key. Enter the 16 digit license key and click **Send**.




5. Click **OK** to confirm.



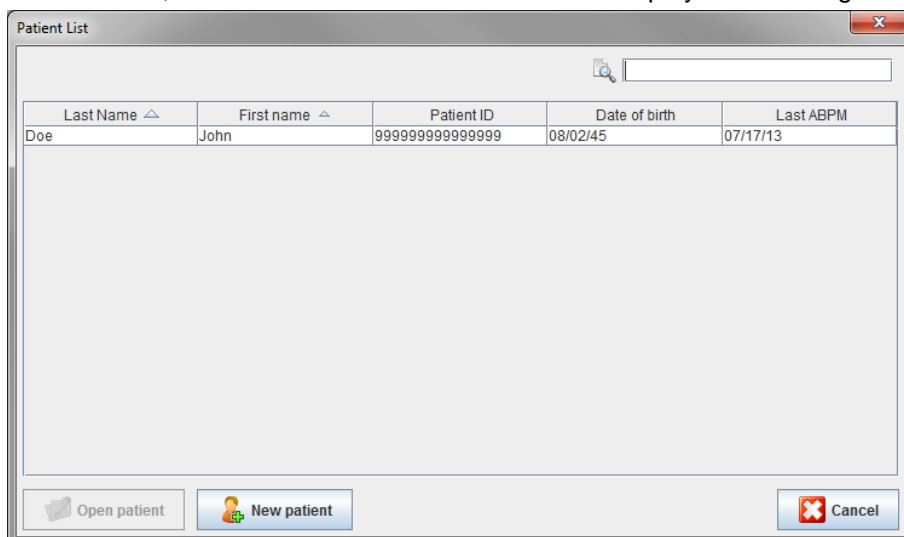
First steps with the sample patient

Once you have successfully installed the **HMS** software, the **HMS** may be tested with the sample patient John Doe.

Displaying the patient

1. Start the **HMS** by double-clicking the  icon located on the computer desktop. The application window will appear.

2. In the toolbar, click the **Patient List**  icon to display the following window:



15 - First steps with the sample patient

3. Select the **John Doe** entry and the click **Open patient**.

Tip Double-click on the patient you selected and the application window will display the patient information.

The screenshot shows the 'Patient information' tab for John Doe. The window title is 'HMS - 5.0 - Welch Allyn'. The top right corner displays 'Patient: John Doe (08/02/45)' and the 'WelchAllyn' logo. The left sidebar contains tabs for 'Patient information', 'Blood Pressure', and 'Pulse wave analysis'. The main content area is divided into several sections:

- Address:** Last Name: Doe, First name: John, Street: Baker Street, Zip Code: 83445, City: London, Country: (dropdown), Phone: +44123456789, Fax number: (empty), Mobile: (empty), e-mail: john@doe.com.
- Patient data:** Patient ID: 9999999999999999, Server PID: (empty), Height [cm]: 180, Weight [kg]: 82.0, BMI: 25.3, Smoker: No, Date of birth [mm/dd/yyyy]: 08/02/1945, Age: 69, Gender: Male, Insurance: (empty), Department/Room: (empty).
- Blood pressure limits:** - ABPM Values - Average Values: Day 135/85 mmHg, Night 120/75 mmHg, Total 130/80 mmHg; - Self measurements: 135/85 mmHg.
- Emergency contacts:** Table with columns: Last Name, First name, Phone, Relationship.
- Medical history:** Table with columns: From, To, Disease, Notes.
- Medication:** Table with columns: From, To, Trade name, Active agent, Dosage.

Each section has a 'New entry' button and a 'Delete entry' button.

The patient's name and date of birth will be displayed on the top right of the application window. The **Patient Information** tab features several areas: Address, Patient data, Emergency contacts, Medical history, Medication and Blood pressure limits.

Displaying the patient's measurement data

1. Click the **Blood Pressure** tab and a list of previous measurements will be shown on the left.

The screenshot shows the 'Blood Pressure' tab. The window title is 'HMS - 5.0 - Welch Allyn'. The top right corner displays 'Patient: John Doe (08/02/45)' and the 'WelchAllyn' logo. The left sidebar contains tabs for 'Patient information', 'Blood Pressure', and 'Pulse wave analysis'. The main content area displays a list of measurements:

Num.	Date	Time	Sys	MAP	Dia	Hr	cSys	cDia	Code	Notes
1	02/27/12	10:44	106	81	60	87	97	61	230	Start einer manuellen Messung.
2	02/27/12	10:45	106	85	67	87	96	68		
3	02/27/12	11:00	100	78	60	85	90	61		
4	02/27/12	11:15	106	82	62	83	97	64		
5	02/27/12	11:33	117	87	62	84				
6	02/27/12	11:45	116	84	57	90	95	62		
7	02/27/12	12:03	137	111	88	89				
8	02/27/12	12:15	120	93	70	84	109	72		
9	02/27/12	12:30	102	81	64	79	92	65		
10	02/27/12	12:48	118	90	68	89				
11	02/27/12	13:00	118	87	60	76	111	62		
12	02/27/12	13:15	102	78	58	76	94	59		
13	02/27/12	13:30	99	76	57	76	91	68		
14	02/27/12	13:45	99	78	60	76	92	61		
15	02/27/12	14:00	114	88	66	77	108	67		
16	02/27/12	14:15	107	85	66	71	98	66		
17	02/27/12	14:30	109	88	70	68	101	70		
18	02/27/12	14:45	116	91	69	71	110	70		
19	02/27/12	15:00	143	100	84	74	134	67		
20	02/27/12	15:15	122	94	70	71	116	71		
21	02/27/12	15:33								
22	02/27/12	15:45	111	88	69	73	104	70		
23	02/27/12	16:03	111	84	60	75				
24	02/27/12	16:18	125	98	75	81				
25	02/27/12	16:30	120	90	64	75	101	68		
26	02/27/12	16:45	110	90	72	76	105	73		
27	02/27/12	17:00	116	90	67	74	106	68		
28	02/27/12	17:15	120	102	86	76	115	88		
29	02/27/12	17:30	117	89	66	83	102	69		
30	02/27/12	17:48								
31	02/27/12	18:00	118	93	72	80	107	73		
32	02/27/12	18:15	119	95	75	79	108	76		
33	02/27/12	18:30	121	93	69	83	111	71		
34	02/27/12	18:45	108	94	81	88	97	62		
35	02/27/12	19:00	124	90	62	86	109	65		
36	02/27/12	19:15	135	98	67	84	123	70		
37	02/27/12	19:30	136	95	60	83	120	63		
38	02/27/12	19:45	127	95	69	86	114	71		
39	02/27/12	20:00	130	95	65	89	117	67		
40	02/27/12	20:15	124	106	91	104	118	93		
41	02/27/12	20:33	143	108	79	102				
42	02/27/12	20:45	131	99	71	99	116	72		
43	02/27/12	20:48	139	103	73	102	122	75		
44	02/27/12	21:03								
45	02/27/12	21:08	126	96	71	115				
46	02/27/12	21:30	108	79	55	90				
47	02/27/12	22:00	98	65	36	84	89	36		
48	02/27/12	22:30	110	79	53	84				
49	02/27/12	23:00	99	72	49	80	92	51		
50	02/27/12	23:30	72	53	37	80				

At the bottom of the table, there are several notes:

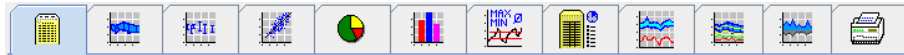
- 2) Pulsbasisbreite ist größer als in 'MAX_BEAT_WIDTH' definiert.
- 3) Oszillation ist zu hoch (Grenzwert).
- 230 Start einer manuellen Messung.
- 3) Oszillation ist zu hoch (Grenzwert).
- 123 Die Tag/Nacht-Taste wurde innerhalb des vorgesehenen Zeitfensters betätigt. Es wurde in den Tag/Nac...

16 - Editing patient information

2. Click to select a measurement. The respective measurement data is then displayed. Highlighted measurement values are values exceeding the specified limit values.
3. For additional analyzes, click the required analysis tab.

Tip If you use the mouse to hover over a symbol, a brief tooltip will appear.

The toolbar with the analysis tabs



Descriptions on the analysis options are detailed in the Analyzing the measurement chapter.

Editing patient information

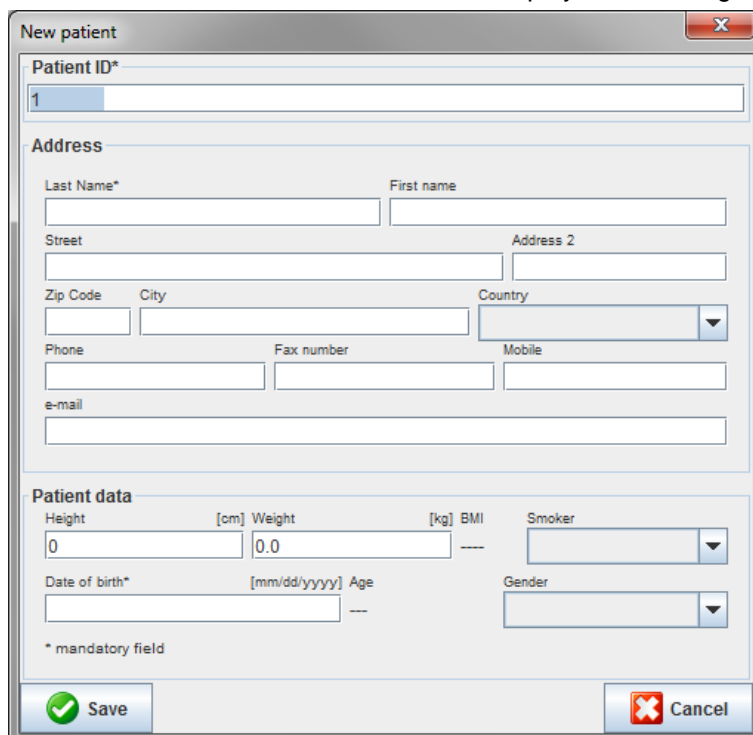
Patient information is stored in a database. You can

- create new patients,
- edit patients data by clicking onto the respective field,
- import already available patient information from other databases.

Note Patient information can always be edited once it has been created.

Creating new patients

In the toolbar, click the **New Patient**  icon to display the following window:



New patient

Patient ID*
1

Address

Last Name* First name
Street Address 2
Zip Code City Country
Phone Fax number Mobile
e-mail

Patient data

Height [cm] Weight [kg] BMI Smoker
0 0.0 ---
Date of birth* [mm/dd/yyyy] Age Gender
--- ---

* mandatory field

Save Cancel

Patient ID, **Last Name** and **Date of birth** are mandatory fields (these information serve as criteria for sorting or searching), all other information are optional.

Tip Use the tab key to jump from one field to the next.

17 - Editing patient information

To save the new patient, click **Save**.

To discard the new patient, click **Cancel**. Either option will return back to the application window.


The screenshot displays the 'Patient Information' tab in the HMS - 5.0 - Welch Allyn application. The interface is divided into several sections: 'Address' with fields for last name, first name, street, zip code, city, country, phone, fax number, and mobile; 'Patient data' with fields for patient ID, server ID, height, weight, BMI, blood pressure, date of birth, age, gender, insurance, and department/room; 'Emergency contacts' with a table for last name, first name, phone, and relationship; 'Medical history' with a table for from, to, disease, and notes; 'Medication' with a table for from, to, trade name, active agent, and dosage; and 'Blood pressure limits' with sections for ABPM values (average and single) and self-measurements. Each section has a 'New entry' button and a 'Delete entry' button.

The **Patient Information** tab displays several areas: Address, Patient data, Emergency contacts, Medical history, Medication and Blood pressure limits.

Selecting existing patients

Select a patient from the patients list previously created in the **HMS** to

- view their previous measurements,
- prepare the ABPM 7100 for this patient,
- transfer the measurement values from the ABPM 7100 to the **HMS**.

In the toolbar, click the **Patient List**  icon to display the list of previously created patient entries.

The screenshot shows the 'Patient List' window. It features a search bar at the top right. Below it is a table with the following data:

Last Name	First name	Patient ID	Date of birth	Last ABPM
Doe	John	9999999999999999	08/02/45	07/17/13
Patient	Test	1	01/01/90	

At the bottom of the window, there are three buttons: 'Open patient' (with a folder icon), 'New patient' (with a plus icon), and 'Cancel' (with a red X icon).

Click to select the appropriate entry and then click **Open patient**.

18 - Editing patient information

To search for a patient follow the steps below:

1. Enter the last name, first name or patient ID in the search field at the top right. The **HMS** will search the database and display the detected patients.
2. Click to select the appropriate entry and then click **Open patient**.
3. The **HMS** returns to the application window.

If the required patient cannot be found, click **New patient** to create a new patient entry.

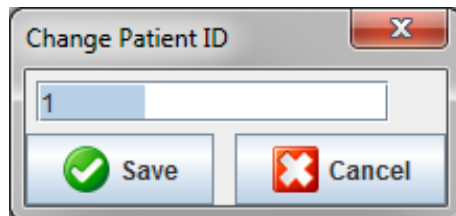
Modifying patient data

To modify an address and/or patient data, enter the new information in the respective fields.

1. To add Emergency contacts, Medical history and Medication, click **New entry**.
2. Enter the new information into the respective popup window.
3. Click **Save** to save the new data.
4. The window closes.

Changing the Patient ID

1. In the menu bar, click **Patient** then **Change ID** to display the following window with the current patient's ID shown.



2. Change the patient's ID.
3. Click **Save** to save the change.

Blood pressure limits

1. In the **Patient Information** tab, click on the field **Blood pressure limits**.
2. Specify the blood pressure limits for the current selected patient in the open editing window. If any measurement results exceed the limit values, the respective results will be marked accordingly in the analysis.

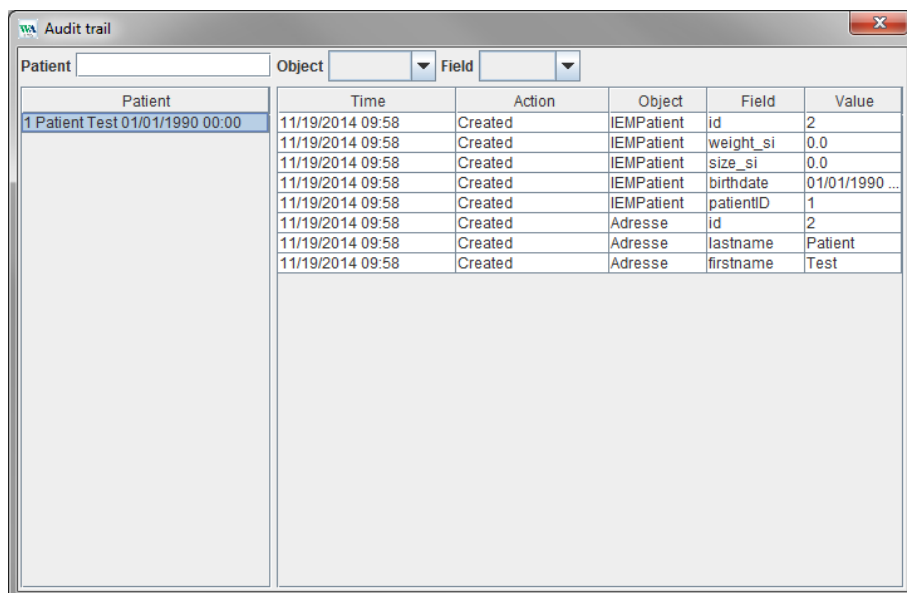
Deleting a patient

1. In the menu bar, click **Patient** then **Delete**.
2. Click **Yes** to confirm.
3. The current selected patient's information is deleted together with all measurement data.

Audit Trail

In the menu bar click **File** and then **Audit trail** to display all changes in the patient master data.

19 - Working with the ABPM 7100



The screenshot shows a window titled 'Audit trail' with a search bar for 'Patient', 'Object', and 'Field'. Below the search bar is a table with the following data:

Patient	Time	Action	Object	Field	Value
1 Patient Test 01/01/1990 00:00	11/19/2014 09:58	Created	IEMPatient	id	2
	11/19/2014 09:58	Created	IEMPatient	weight_si	0.0
	11/19/2014 09:58	Created	IEMPatient	size_si	0.0
	11/19/2014 09:58	Created	IEMPatient	birthdate	01/01/1990 ...
	11/19/2014 09:58	Created	IEMPatient	patientID	1
	11/19/2014 09:58	Created	Adresse	id	2
	11/19/2014 09:58	Created	Adresse	lastname	Patient
	11/19/2014 09:58	Created	Adresse	firstname	Test

Working with the ABPM 7100

Pairing via cable

Before 24-hour measurement:

When using the ABPM 7100 with cable connection, perform the following steps:

Pairing the computer to the ABPM 7100 via the USB interface cable

On the ABPM 7100:

1. Ensure that the ABPM 7100 is powered off.
2. Insert the USB interface cable into the computer's USB port.
3. Insert the USB interface cable plug into the data port at the bottom of the ABPM 7100.

Note The red dot on the plug must align with the red dot on the data port.

4. Switch on the ABPM 7100. The letters "co" will appear on the display.

Configuring the interface between the ABPM 7100 and the HMS

Setup conditions:

- The ABPM 7100 is connected to the computer.
- Both the ABPM 7100 and the computer are switched on.

On the computer:

1. Start the **HMS**. If the **HMS** is set appropriately, the **Patient List** window will appear. In this case select a patient.
2. In the menu bar, click **Settings** and then **Port settings**.
3. In the **Port settings** window, click the **Serial/USB** tab.

Preparing the ABPM 7100 for 24-hour measurement

Setup conditions:

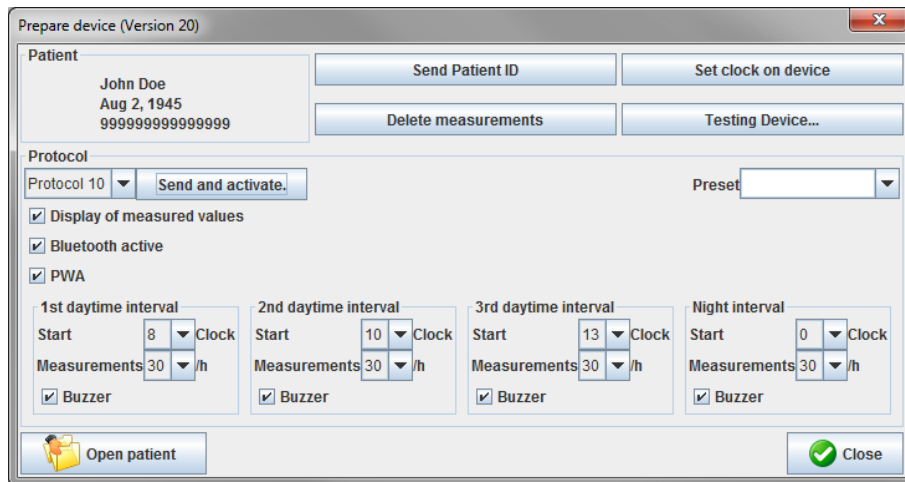
- The ABPM 7100 is connected to the computer.
- Both the ABPM 7100 and the computer are switched on.

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Note Always use fully charged batteries for a new measurement. Ensure the correct polarity when inserting the batteries.

On the computer:

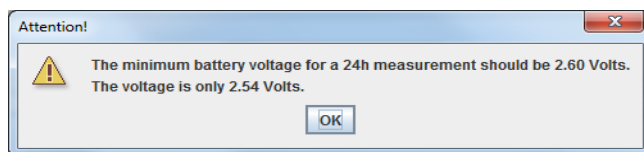
1. Start the **HMS**.
2. Select a patient.
3. In the toolbar, click the **Prepare device**  icon to display the following window:




The 'Prepare device (Version 20)' window contains the following elements:

- Patient section:** Displays 'John Doe', 'Aug 2, 1945', and '9999999999999999'. Buttons include 'Send Patient ID', 'Set clock on device', 'Delete measurements', and 'Testing Device...'.
- Protocol section:** A dropdown menu set to 'Protocol 10' with a 'Send and activate.' button and a 'Preset' dropdown.
- Options section:** Checkboxes for 'Display of measured values', 'Bluetooth active', and 'PWA'.
- Intervals section:** Four columns for '1st daytime interval', '2nd daytime interval', '3rd daytime interval', and 'Night interval'. Each column has 'Start' (dropdown), 'Clock' (dropdown), 'Measurements' (dropdown), and a 'Buzzer' checkbox.
- Bottom section:** 'Open patient' button with a folder icon and a 'Close' button with a green checkmark icon.

Note If the battery voltage in the measurement device is insufficient for a 24-hour measurement, the following warning will appear.



4. Specify the protocol for 24-hour measurement.
5. Click **Set clock on device**.
6. Click **Send Patient ID**.
7. Click **Send and activate**.
8. Click **Close**.
9. In the toolbar, click  to quit the **HMS**.

On the ABPM 7100:

10. Switch off the ABPM 7100.
11. Disconnect the cable by removing the plug from the data port.

Starting 24-hour measurement

On the ABPM 7100:

You need to perform the steps described below to connect the computer to the ABPM 7100. Please read the directions for use for the ABPM 7100 up to the chapter **Measurement Process**.

After 24-hour measurement

When using the ABPM 7100 with cable connection, perform the following steps:

21 - Working with the ABPM 7100

Connecting the computer to the ABPM 7100 via cable after a 24-hour measurement

After 24-hour measurement, transfer the data from the ABPM 7100 to the **HMS**.

1. Ensure the ABPM 7100 is powered off.
2. Remove the ABPM 7100 from the patient (remove the cuff and disconnect the ABPM 7100).
3. Connect the ABPM 7100 to the computer using the USB interface cable:
 - a. Insert the USB interface cable into the computer's USB port.
 - b. Insert the USB interface cable plug into the data port at the bottom of the ABPM 7100.

Note The red dot on the plug must align with the red dot on the data port.

4. Switch on the ABPM 7100.
5. The letters "**co**" will be displayed on the ABPM 7100 LCD.





For further information on your ABPM 7100 please refer to the directions for use of the ABPM 7100.

Transferring 24-hour measurement values out from the ABPM 7100

Ensure the ABPM 7100 is connected to the computer and both the ABPM 7100 and the computer are switched on.

On the computer:

1. Start the **HMS**.
2. In the toolbar, click the **Patient List**  icon to display the **Patient List** window.
3. Select a patient.
4. In the toolbar, click the **Upload device**  icon. The **HMS** will prompt the user: "Assign measurement results to patient with patient ID XXX?"
5. Click **Yes**. The **HMS** will prompt the user: "Delete Patient ID and measurement results from the ABPM 7100?"

Note Normally the measurement results from the ABPM 7100 are deleted once the results are transferred out. When preparing the ABPM 7100 for a "new" patient, the **HMS** will indicate any existing measurement results remaining in the ABPM 7100 from a previous patient.

6. Click **Yes** to delete the measurements results or click **No** to keep the measurement results on the ABPM 7100. The **Measurement series** window appears.

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Measurement series

Please choose the starting times of the Day/Night intervals or type them in manually.

Start of daytime interval [HH:mm] 07:00

The Day/Night key was not pressed

Start night interval [HH:mm] 22:00

Day / Night button has been pressed 1 times

Findings/Notes

Protocol 11 Transmission 03/02/2012 Serial number C08215

Save Cancel

7. If necessary, change the times for the daytime and night interval.
8. Enter a note.
9. Click **Save** to confirm and the transmitted measurement values are displayed as a table of measurements.

On the ABPM 7100:

10. Switch off the ABPM 7100.
11. Disconnect the USB interface cable (remove the plug from the data port).



For further measurement series analyzes, refer to the chapter on **Analyzing Measurements**.

Pairing via Bluetooth®

Before 24-hour measurement

Please perform the following steps when using the ABPM 7100 with Bluetooth® connection:

Configuring the interface between ABPM 7100 and HMS

To configure the interface between ABPM 7100 and **HMS** ensure the computer is switched on and the Bluetooth® driver is installed.







For further information on your ABPM 7100 please refer to the directions for use of the ABPM 7100.

On the computer:

1. Start the **HMS**. If the **HMS** is set appropriately, the **Patient List** window will appear. In this case select a patient.
2. In the menu bar, click **Settings** and then **Port settings**.
3. In the **Port settings** window, click the **Bluetooth®** tab.
4. Click **Add device**. The following instruction appears: "Switch on the ABPM 7100 and change into **"PAir"** mode".

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On the ABPM 7100:

5. Switch on the ABPM 7100.
6. Switch the ABPM 7100 into Pairing mode:
 - i. Press and hold  and then press .
 - ii. Keep  pressed until the letters “**PAIr**” start flashing on the LCD display.
 - iii. Press . “**PAIr**” stops blinking and the buzzer sounds.

On the computer:

7. Click **OK**. The **Bluetooth® device search** appears. After a moment the serial number of the ABPM 7100 (e.g. WSTXXX) appears in the application window.
8. Click the serial number.
9. Click **Pairing**. The following message appears: “Pairing successful”.
10. Click **OK** to confirm and the **Device Connection** window appears.
11. Click **Save**.

On the ABPM 7100:

12. The buzzer sounds.

On the computer:

13. The measurement device appears in the **Port settings** window on the **Bluetooth®** tab. Click **Save**.

On the ABPM 7100:

14. Switch off the ABPM 7100.

The Bluetooth® interface between the ABPM 7100 and the **HMS** is now configured. From now on, the **HMS** will recognize the ABPM 7100 as soon as the ABPM 7100 is in communication mode “**bt**”.

Preparing the ABPM 7100 for 24-hour measurement

Ensure the ABPM 7100 is switched off and the computer is switched on. The interface between ABPM 7100 and the **HMS** must already be configured.



For further information on your ABPM 7100 please refer to the directions for use of the ABPM 7100.




On the ABPM 7100:

1. Switch on the ABPM 7100.


On the computer:

2. Start the **HMS**.
3. In the toolbar, a green **Bluetooth®**  icon signals the active Bluetooth® connection.
4. Select a patient.

On the ABPM 7100:

5. Press and hold  and then press .
6. Press . The letters “**bt**” flash on the display.

24 - Working with the ABPM 7100

- Press . "bt" no longer flashes and the buzzer sounds.

On the computer:

- The **Device Action** window appears.

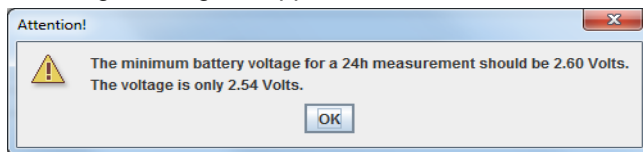
On the ABPM 7100:

- The buzzer sounds twice.

On the computer:

- Click **Prepare device** to display the **Prepare device** window.

Note If the battery voltage in the measurement device is insufficient for a 24-hour measurement, the following warning will appear.



Note Before use, make sure that any previous measurement results stored in the ABPM 7100 are deleted to avoid incorrect value assignment. You can also delete measurement values manually on the device, please refer to the ABPM 7100 directions for use.

- Specify the protocol for 24-hour measurement.
- Click **Set clock on device**.
- Click **Send Patient ID**.
- Click **Send and activate**.
- Click **Save**.

On the ABPM 7100:

- The buzzer sounds
- The letters "bt End" flash in the LCD display, followed by the time.

On the computer:

- In the toolbar, click  to exit the **HMS**.


Starting 24-hour measurement

Ensure the ABPM 7100 is switched on.



For further information on your ABPM 7100 please refer to the directions for use of the ABPM 7100.

On the ABPM 7100:

- Set up the ABPM 7100 on the patient (position the cuff and connect it to the ABPM 7100).
- Press  for manual measurement to ensure that the ABPM 7100 is functional.
- Wait for the first manual measurement to be completed. If the measurement is acceptable, the patient can leave. A successful measurement is required for protocol activation.

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After 24-hour measurement

Please perform the following steps when using the ABPM 7100 with Bluetooth® connection:

1. Ensure the ABPM 7100 is powered off.
2. Remove the ABPM 7100 from the patient (remove the cuff and disconnect the ABPM 7100).





Transferring out 24-hour measurement results from the ABPM 7100 via Bluetooth®

Ensure both the ABPM 7100 and the computer are switched on. The interface between ABPM 7100 and the **HMS** must already be configured.

On the computer:

1. Start the **HMS**.
2. In the toolbar, a green **Bluetooth®**  icon signals the active Bluetooth® connection.

On the ABPM 7100:

3. Press and hold  and then press .
4. Press . The letters “**bt**” flash on the display.
5. Press . “**bt**” stops flashing and the buzzer sounds. The **Device Action** window appears.

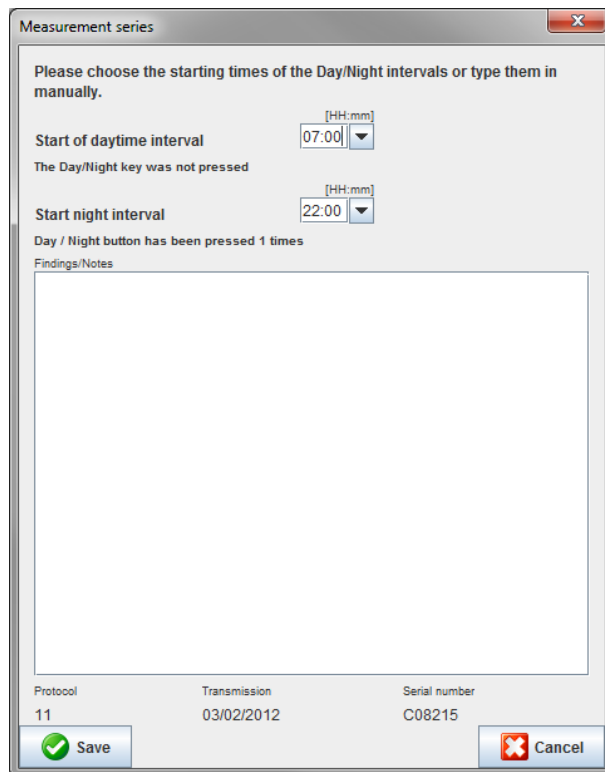
On the computer:

6. Click on **Read-out of values**. The **HMS** will prompt the user: “Assign measurement data to patient with patient ID XXX?”
7. Click **Yes** to confirm. After data transmission, the **Measurement series** window appears.
8. If necessary, change the times for the daytime and nighttime interval.
9. Click **Save**. The **HMS** will prompt the user: “Delete Patient ID and measurement data from measurement device?”

Note Normally the measurement results from the ABPM 7100 are deleted once the results are transferred. When preparing the ABPM 7100 for a “new” patient, the **HMS** will indicate any existing measurement results remaining in the ABPM 7100 from a previous patient.

10. Click **Yes** to delete the measurements results or click **No** to keep the measurement results on the ABPM 7100. The Measurement Series window appears.

26 - Preparing the ABPM 7100 for measurement



11. If necessary, change the times for the daytime and night interval.
12. Enter a note.
13. Click **Save** to confirm and the transmitted measurement values are displayed as a table of measurements.

On the ABPM 7100:

14. The buzzer sounds.
15. The letters "**bt End**" appear on the display, followed by the time.
16. Switch off the ABPM 7100.



For further measurement series analyzes, refer to the chapter on **Analyzing Measurements**.

Preparing the ABPM 7100 for measurement

Before performing a measurement on a patient, send via the **HMS** the information on the planned measurement to the ABPM 7100.

Ensure that the **HMS** has started and the ABPM 7100 is switched on and connected to the computer. The interface between the ABPM 7100 and the **HMS** must already be configured.

Please go through the following steps:

- Specify the measurement protocol.
- Set the ABPM 7100 clock.
- Accept the patient ID.
- Perform device tests.
- Delete existing measurements.
- Start 24-hour measurement.

1. Select a patient.

2. In the toolbar, click the **Prepare device**  icon to display the following window.

27 - Preparing the ABPM 7100 for measurement

Setting the measurement protocol

The procedure for 24-hour measurement can be set here. In total 11 different protocols are provided. The protocols 1, 2, 10 and 11 can be adjusted individually.

Additionally, protocol 10 automatically sends measurement values to the doctor's computer via Bluetooth® after measurement. It is recommended to use protocol 10 for monitoring at the doctor's office.

Additionally, protocol 11 activates the Pulse Wave Analysis (PWA).

Selecting the protocol

1. In the protocol drop-down menu, click on the required protocol.
2. For protocols 1, 2, 10 and 11 under daytime and nighttime interval, determine the following:
 - The time frame (start of interval).
 - The number of measurements within the interval.
 - Whether the measurement values are displayed on the ABPM 7100 (measurement display value).
 - Whether an audible signal (buzzer) sounds during measurement.

Sending the protocol

1. Click **Send and activate**.
2. Click **Yes** to confirm.

Setting the ABPM 7100 clock

The computer's time will be adopted by the ABPM 7100.

1. Click **Set clock on device**.
2. Click **Ok** to confirm and the ABPM 7100 displays the adopted time.

Transmitting the Patient ID

The patient ID of the selected patient should be saved in the ABPM 7100. When the 24-hour measurement values are transferred, the **HMS** will automatically recognize the patient.

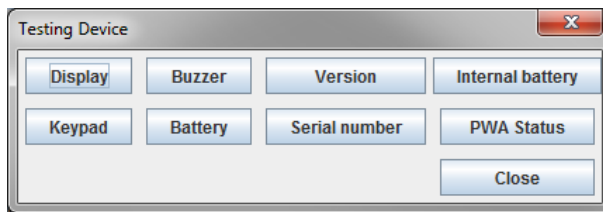
1. Click **Send Patient ID**.
2. Click **Ok** to confirm.

Testing the ABPM 7100

Perform the following steps to ensure that the ABPM 7100 is fully functional.

1. Click **Testing Device** to display the following window.

28 - Preparing the ABPM 7100 for measurement



2. Click on the appropriate function keys.
3. Click **Ok** to confirm.
4. Click **Close** to complete the testing.

Deleting old measurements

The measurement results in the ABPM 7100 are usually deleted once they have been transferred to the computer. When preparing the ABPM 7100 for a “new” patient, the **HMS** will indicate any existing measurement results remaining in the ABPM 7100 from a previous patient.

To remove existing measurement results in the ABPM 7100:

1. Click **Delete measurements**.
2. Click **Yes** to confirm.

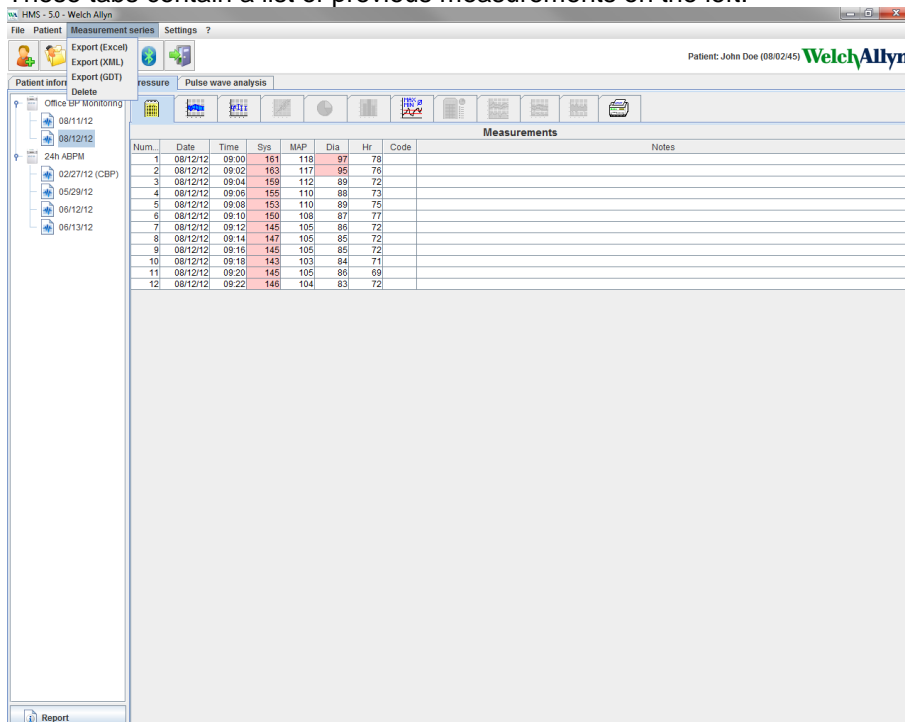
Completing ABPM 7100 preparation

1. Click **Close** and the **Prepare device** window disappears.
2. Disconnect the ABPM 7100 from the computer.

Exporting measurement results

Measurement results from a 24-hour measurement which has been transferred from the ABPM 7100 to the **HMS** for analysis can be stored in a file. With the help of this file, there is the option to transfer the measurement results into your patient management system.

1. Select a patient
2. In the application window, click on the **Blood Pressure or Pulse wave analysis** tab.
3. These tabs contain a list of previous measurements on the left.















29 - Analyzing the measurement

4. Click to select the measurement results to be exported.
5. In the menu bar, click **Measurement series** and then **Export** (Excel), (XML) and (GDT). The **Export measurement series** window appears.
6. Set the directory and name for the file.
7. Click **Save**.

Analyzing the measurement

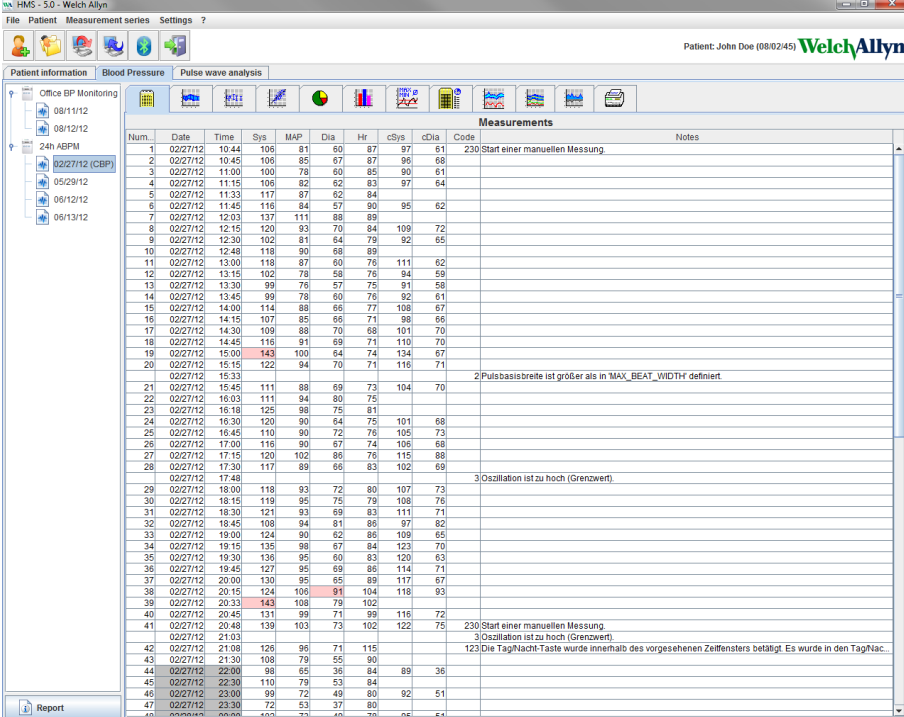
Once the measurement values from the ABPM 7100 have been transferred and stored from the ABPM 7100 to the **HMS**, the following analyzes and functions are available for measurement analysis and are described in this chapter:

Tab	Analysis
	Measurements
	Trends
	Bar chart
	Scatter Points
	Exceeding norms
	Frequency distribution
	Summary
	Hourly Intervals
	Rise and Fall
	Trends (PWA)
	Amplification
	Print

1. Select the required patient.
2. In the application window, click on the **Blood Pressure** tab. The **Blood Pressure** tab contains a list of previous measurements on the left.

30 - Analyzing the measurement

- Click on a measurement to display the associated table of measurements.



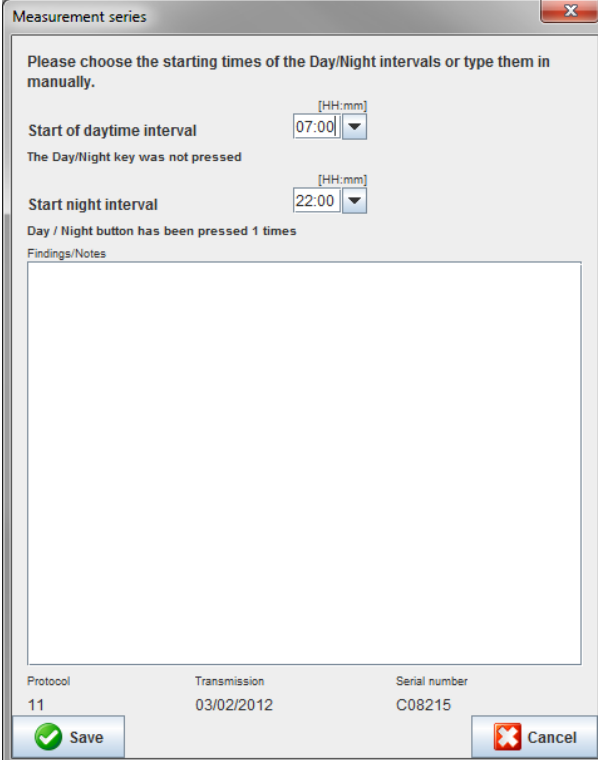
Num.	Date	Time	Sys	MAP	Dia	Hr	cSys	cDia	Code	Notes
1	02/27/12	10:44	106	81	60	87	97	61	230	Start einer manuellen Messung.
2	02/27/12	10:45	106	85	67	87	96	68		
3	02/27/12	11:00	100	78	60	85	90	61		
4	02/27/12	11:15	106	82	62	83	97	64		
5	02/27/12	11:33	117	87	62	84				
6	02/27/12	11:45	116	84	57	90	95	62		
7	02/27/12	12:03	137	111	88	88				
8	02/27/12	12:15	120	93	70	84	109	72		
9	02/27/12	12:30	102	81	64	79	92	65		
10	02/27/12	12:46	118	90	68	89				
11	02/27/12	13:00	118	87	60	76	111	62		
12	02/27/12	13:15	102	78	58	76	94	59		
13	02/27/12	13:30	99	76	57	75	91	58		
14	02/27/12	13:45	99	78	60	75	92	61		
15	02/27/12	14:00	114	88	66	77	108	67		
16	02/27/12	14:15	107	85	66	71	98	66		
17	02/27/12	14:30	109	88	70	68	101	70		
18	02/27/12	14:45	116	91	69	71	110	70		
19	02/27/12	15:00	143	100	64	74	134	67		
20	02/27/12	15:15	122	84	70	71	116	71		2 Pulsbasisbreite ist größer als in MAX_BEAT_WIDTH definiert.
21	02/27/12	15:33								
22	02/27/12	15:45	111	88	69	73	104	70		
23	02/27/12	16:03	111	94	80	75				
24	02/27/12	16:18	125	98	75	81				
25	02/27/12	16:30	120	90	64	75	101	68		
26	02/27/12	16:45	110	90	72	76	105	73		
27	02/27/12	17:00	116	90	67	74	106	68		
28	02/27/12	17:15	120	102	86	76	115	88		
29	02/27/12	17:30	117	89	66	83	102	69		3 Oszillation ist zu hoch (Grenzwert).
30	02/27/12	17:48								
31	02/27/12	18:00	118	93	72	80	107	73		
32	02/27/12	18:15	119	95	75	79	108	76		
33	02/27/12	18:30	121	93	69	83	111	71		
34	02/27/12	18:45	108	94	81	86	97	82		
35	02/27/12	19:00	124	90	62	86	109	65		
36	02/27/12	19:15	135	98	67	84	123	70		
37	02/27/12	19:30	136	95	60	83	120	63		
38	02/27/12	19:45	127	95	69	86	114	71		
39	02/27/12	20:00	130	95	65	89	117	67		
40	02/27/12	20:15	124	106	91	104	118	93		
41	02/27/12	20:33	143	108	79	102				230 Start einer manuellen Messung.
42	02/27/12	20:48	139	103	73	102	122	75		123 Die Tag/Nacht-Taste wurde innerhalb des vorgesehenen Zeitfensters betätigt. Es wurde in den Tag/Nacht...
43	02/27/12	21:08	128	96	71	115				
44	02/27/12	21:30	108	79	55	90				
45	02/27/12	22:00	98	65	36	84	89	36		
46	02/27/12	22:30	110	79	53	84				
47	02/27/12	23:00	99	72	49	80	92	51		
48	02/27/12	23:30	72	53	37	80				

The highlighted values are measurement values exceeding the specified limit values.

- To display additional analyzes, click on the required analysis tab.

Enter the results of the measurement series.

- Double-click on the measurement and the **Measurement series** window appears.



Measurement series

Please choose the starting times of the Day/Night intervals or type them in manually.

Start of daytime interval [HH:mm] 07:00

The Day/Night key was not pressed

Start night interval [HH:mm] 22:00

Day / Night button has been pressed 1 times

Findings/Notes

Protocol 11 Transmission 03/02/2012 Serial number C08215


Save Cancel

- Enter your notes.
- Click **Save** to accept the notes and the **Measurement series** window disappears.

31 - Analyzing the measurement

The Measurements tab

The **Measurements** tab lists all measurement values of a measurement series in table format.

To display the table of measurements, click on the **Measurements**  tab.

Measurements											
Num.	Date	Time	Sys	MAP	Dia	Hr	cSys	cDia	Code	Notes	
1	02/27/12	10:44	106	81	60	87	97	61	230	Start einer manuellen Messung.	
2	02/27/12	10:45	106	85	67	87	96	68			
3	02/27/12	11:00	100	78	60	85	90	61			
4	02/27/12	11:15	106	82	62	83	97	64			
5	02/27/12	11:33	117	87	62	84					
6	02/27/12	11:45	116	84	57	90	95	62			
7	02/27/12	12:03	137	111	88	89					
8	02/27/12	12:15	120	93	70	84	109	72			
9	02/27/12	12:30	102	81	64	79	92	65			
10	02/27/12	12:48	118	90	68	89					
11	02/27/12	13:00	118	87	60	76	111	62			
12	02/27/12	13:15	102	78	58	76	94	59			
13	02/27/12	13:30	99	76	57	75	91	58			
14	02/27/12	13:45	99	78	60	76	92	61			
15	02/27/12	14:00	114	88	66	77	108	67			
16	02/27/12	14:15	107	85	66	71	98	66			
17	02/27/12	14:30	109	88	70	68	101	70			
18	02/27/12	14:45	116	91	69	71	110	70			
19	02/27/12	15:00	143	100	64	74	134	67			
20	02/27/12	15:15	122	94	70	71	116	71			
21	02/27/12	15:33							2	Pulsbasisbreite ist größer als in 'MAX_BEAT_WIDTH' definiert.	
22	02/27/12	15:45	111	88	69	73	104	70			
23	02/27/12	16:03	111	94	80	75					
24	02/27/12	16:18	125	98	75	81					
25	02/27/12	16:30	120	90	64	75	101	68			
26	02/27/12	16:45	110	90	72	76	105	73			
27	02/27/12	17:00	116	90	67	74	106	68			
28	02/27/12	17:15	120	102	86	76	115	88			
29	02/27/12	17:30	117	89	66	83	102	69			
30	02/27/12	17:48							3	Oszillation ist zu hoch (Grenzwert).	
31	02/27/12	18:00	118	93	72	80	107	73			
32	02/27/12	18:15	119	95	75	79	108	76			
33	02/27/12	18:30	121	93	69	83	111	71			

The highlighted values are measurement values exceeding the specified limit values.

To enter measurement notes:

1. Click onto the required line in the Notes column.
2. Enter your note.
3. Press the Enter key.

Excluding measurements:

If any outlier measurement value that would falsify a representative long-term analysis, it can be excluded.

Click onto the number of the respective column. The measurement disappears and the measurement value will be excluded from statistical analysis. To include the measurement values just click on the line again.

Printing the table of measurements:


Click the **Print**  tab.

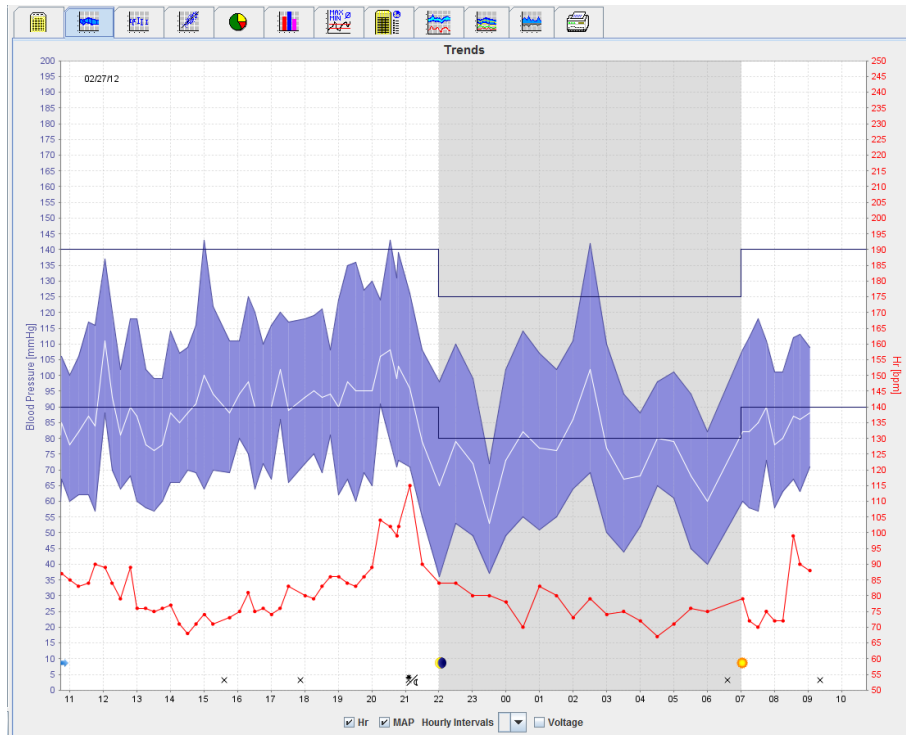
The Trends tab

These measurement values are graphically displayed in a diagram as a function of time:

- Systolic values
- Average Values
- Diastolic Values
- Heart rate

32 - Analyzing the measurement

To display the measurement values, click on the **Trends**  tab.



- The left y-axis with the unit mmHg applies to the systolic, diastolic and average values (blood pressure values).
- The right y-axis with the unit bpm applies the heart rate.
- The x-axis applies to the daytime. The four adjustable daytime intervals for measurements are highlighted. Manual measurements are marked with "M".
- The upper blood pressure limits (systolic, diastolic) are displayed as horizontal set point curves.

Note The blood pressure limits can be specified in the **Patient Information** tab in the **Blood pressure limits** section.

Showing and hiding the heart rate

Click the option field **Hr**.

Showing and hiding average values

Click the option field **MAP**.

Showing and hiding average values

In the drop-down field **Hourly Intervals**, click the required number of hours.

Battery Voltage

Select the option field **Voltage**. The battery voltage is displayed as a 24-hour curve parallel to the blood pressure.

Displaying individual values

1. In the diagram, click to select the desired time. A vertical line appears and the measurement values are displayed in a window. To see adjacent measurement values, move the mouse over the diagram. The vertical line follows the movement of the mouse and the respective values are displayed.
2. Click again to deactivate the display.

33 - Analyzing the measurement

Zooming into (enlarging) the diagram

Click onto the diagram and hold down the left mouse button and drag from the left to right to draw an enlargement section.


Zooming out (restore original size) of the diagram

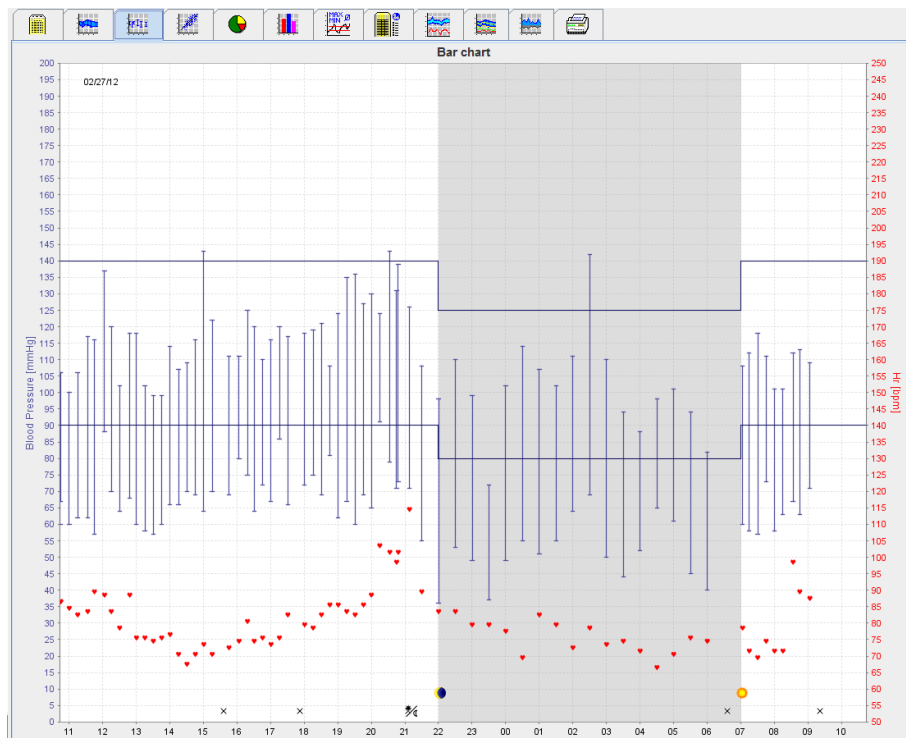
Click onto the diagram and hold down the left mouse button and drag from the right to left to restore back to the original size.

The Bar Chart tab

These measurement values are graphically displayed in a diagram as a function of time:

- Systolic values
- Average Values
- Diastolic Values
- Heart rate

To display the measurement values, click on the **Bar Chart**  tab.



- The left y-axis with the unit mmHg applies to the systolic, diastolic and average values (blood pressure values).
- The right y-axis with the unit bpm applies the heart rate.
- The x-axis applies to the daytime. The four adjustable daytime intervals for measurements are highlighted. Manual measurements are marked with "M".
- The upper blood pressure limits (systolic, diastolic) are displayed as horizontal set point curves.

Note The blood pressure limits can be specified in the **Patient Information** tab in the **Blood Pressure Limits** section.

Zooming into (enlarging) the diagram

Click onto the diagram and hold down the left mouse button and drag from the left to right to draw an enlargement section.


34 - Analyzing the measurement

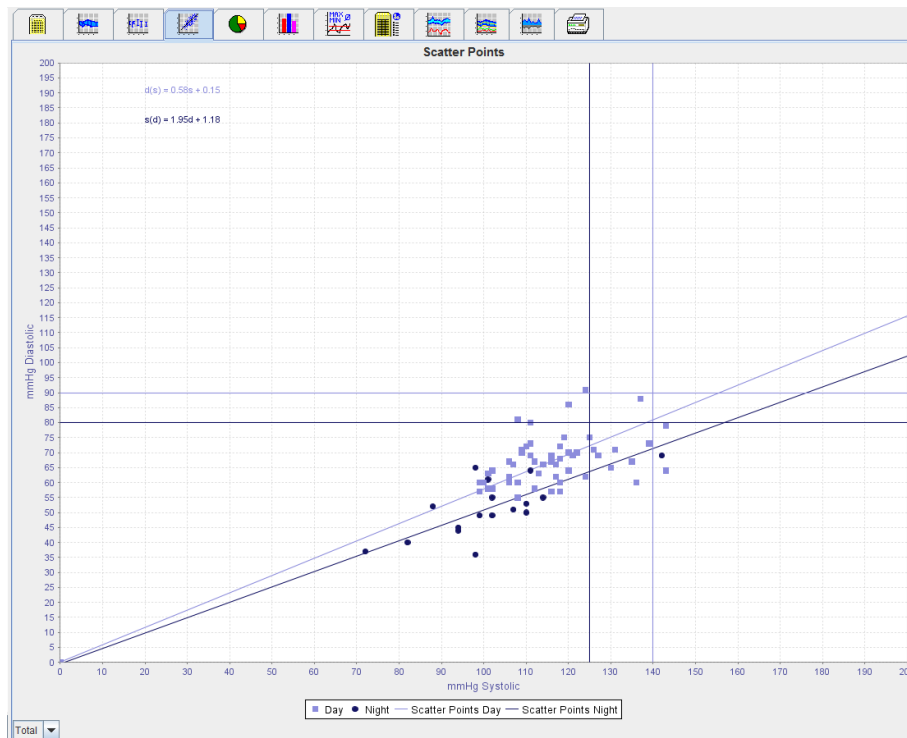
Zooming out (restore original size) of the diagram

Click onto the diagram and hold down the left mouse button and drag from the right to left to restore back to the original size.

The Scatter Points tab

This diagram shows the correlation between systolic and diastolic blood pressure. Each point corresponds to one measurement.

To display the correlation, click on the **Scatter Points**  tab.



- The y-axis applies to diastolic values.
- The x-axis applies to systolic values.
- Blood pressure limits are displayed as horizontal (systolic) and vertical (diastolic) set point curves.

Note The blood pressure limits can be specified in the **Patient Information** tab in the **Blood Pressure Limits** section.

Showing and hiding Total / Day / Night measurements


Use the drop-down field on the bottom left to display the required measurement (total, day, night).

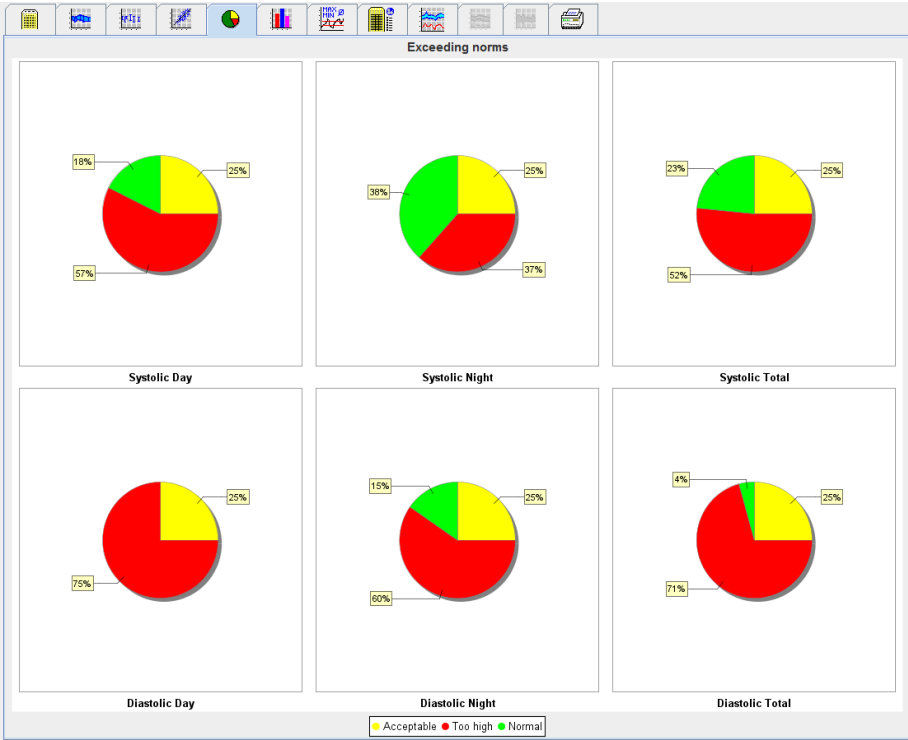
The Exceeding norms tab

The values of a measurement series are analyzed according to specified blood pressure limits. Various pie charts show the percentages of acceptable, exceeded and normal measurement values.

Note The blood pressure limits can be specified in the **Patient Information** tab in the **Blood Pressure Limits** section.


35 - Analyzing the measurement

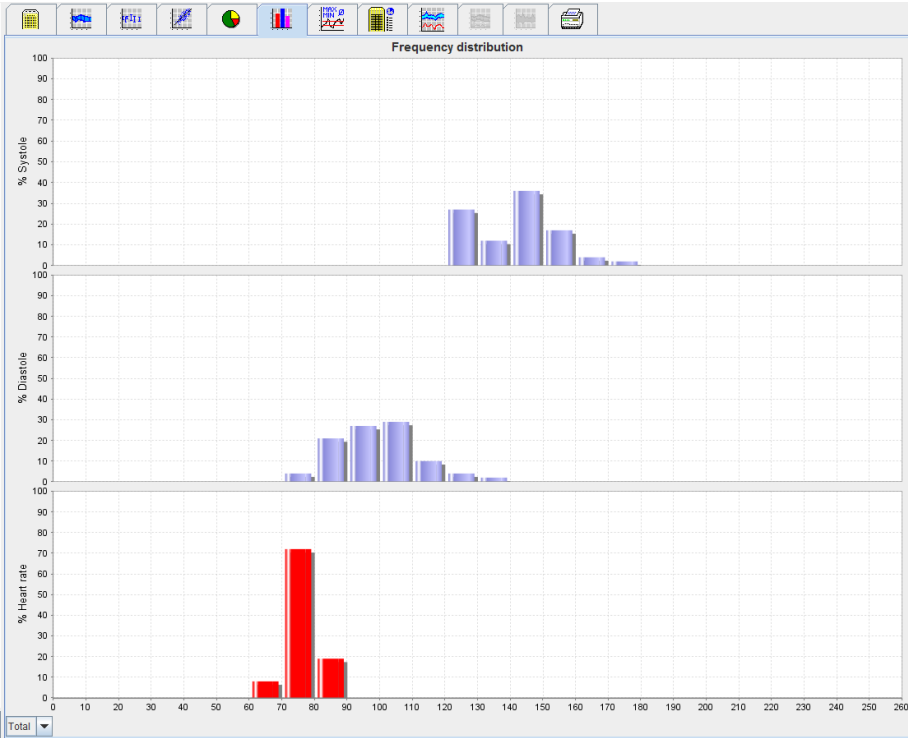
To display the exceeded limit values, click the **Exceeding norms**  tab.



The Frequency Distribution tab

Frequency distributions of systolic and diastolic measurement values, as well as heart rate, are displayed as histograms. Each bar diagram contains the proportional percentages of 10 units, i.e. 80-89, 90-99 etc.

To display the frequency distribution, click on the **Frequency distribution**  tab.



36 - Analyzing the measurement

Selecting measurement values for analysis

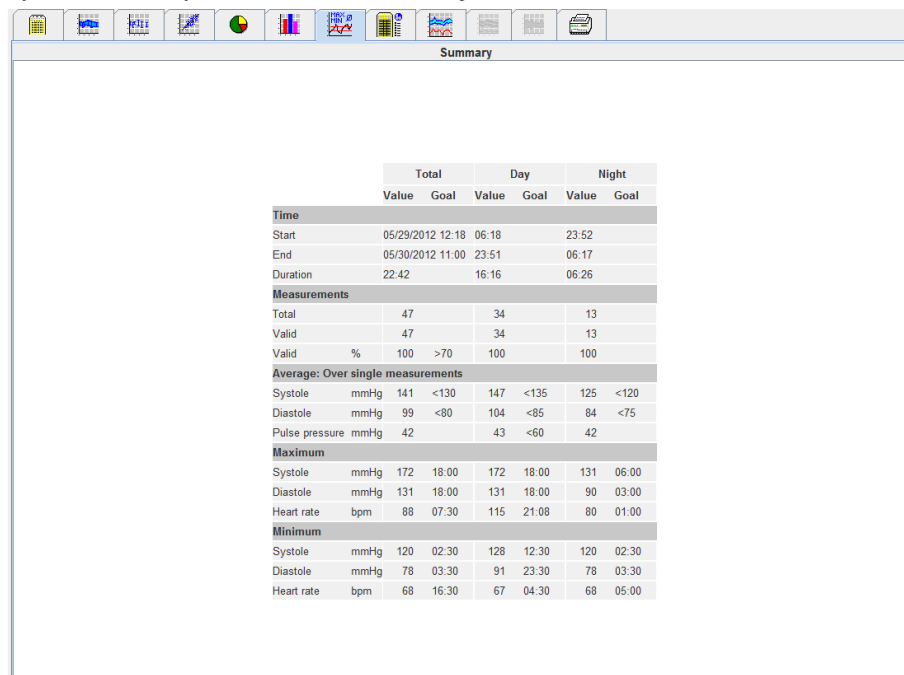
Use the drop-down field on the bottom left to display the required measurement (total, day, night). In the display for day and night, vertical lines indicate blood pressure limits.

Note The blood pressure limits can be specified in the **Patient Information** tab in the **Blood pressure limits** section.

The Summary tab

The summary contains important statistic statements on systolic and diastolic blood pressure. Values for day and night are displayed respectively.

To display the summary, click on the **Summary**  tab.



With Average, the patient's average values and target values are displayed. The blood pressure limits set for this patient are used as the target value.

Note The blood pressure limits can be specified in the **Patient Information** tab in the **Blood pressure limits** section.

With Day/Night Decrease, the percentage in decrease of the average blood pressure values (= average values) between day and night is shown.

Printing the summary


Click the **Print**  tab.

37 - Analyzing the measurement

The Hourly Intervals tab

Displaying hourly average values

This analysis lists all hourly average blood pressure and pulse values in table form.

To display the hourly average values, click on the **Hourly Intervals**  tab.

Hourly Intervals							
Time	Systole	Std. Dev.	Diastole	Std. Dev.	Heart rate	Std. Dev.	Number
0 - 1h	127	1.0	83	1.0	74	0.5	2
1 - 2h	128	1.0	86	2.5	80	0.5	2
2 - 3h	122	2.5	86	2.0	76	3.5	2
3 - 4h	125	3.0	84	6.0	74	0.5	2
4 - 5h	124	3.0	83	1.0	76	1.5	2
5 - 6h	123	0.0	80	0.5	69	1.0	2
6 - 7h	138	6.5	91	3.0	79	3.0	2
7 - 8h	156	2.5	110	7.0	85	3.0	2
8 - 9h	156	7.0	116	12.0	84	1.5	2
9 - 10h	146	2.0	104	1.5	82	5.0	2
10 - 11h	150	2.0	106	4.0	78	1.5	2
11 - 12h	144	0.0	98	0.0	81	0.0	1
12 - 13h	136	8.0	104	4.0	74	1.5	2
13 - 14h	144	10.5	107	5.0	72	2.0	2
14 - 15h	142	0.0	100	2.5	73	1.0	2
15 - 16h	150	5.0	108	3.5	74	4.5	2
16 - 17h	144	1.5	102	3.5	70	2.0	2
17 - 18h	146	8.5	101	7.0	75	3.0	2
18 - 19h	169	3.0	128	3.5	76	1.5	2
19 - 20h	152	4.0	108	6.0	77	1.0	2
20 - 21h	147	5.0	101	7.0	80	2.5	2
21 - 22h	144	0.5	98	0.5	76	2.5	2
22 - 23h	140	2.0	92	0.5	72	1.0	2
23 - 24h	134	1.0	92	1.5	70	1.5	2

Base of mean value (h)

Editing the calculation basis for hourly intervals

Click the required hours (1, 2, 3, 4, 6, 8) in the drop-down field **Base of mean value (h)**. Time intervals are displayed in the left “Time” column. The average hourly value is recalculated.


Printing hourly intervals

Click the **Print**  tab.

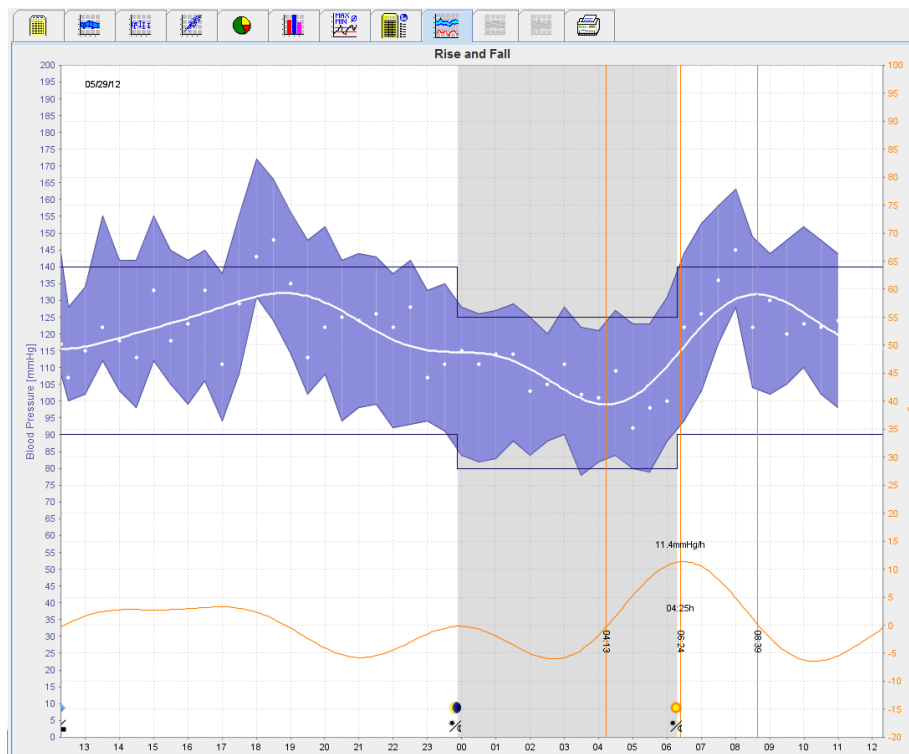
The Rise and Fall tab

This analysis is used to monitor the increase in morning blood pressure. These measurement values are graphically displayed in a diagram as a function of time:

- Systolic values
- Average values
- Diastolic values
- Heart rate

To display the rise and fall in blood pressure, click the **Rise and Fall**  tab.

38 - Analyzing the measurement



- The left y-axis with the unit mmHg applies to the systolic, diastolic and average values (blood pressure values).
- The right y-axis with the unit mmHg/h applies to the change in blood pressure.
- The x-axis applies to the time. Intervals for increases in morning blood pressure are highlighted.
- The bottom curve displays the smoothened course of blood pressure. Blood pressure data of the average blood pressure are transformed into the frequency range by Fourier analysis.
- High frequencies are neglected, resulting in the displayed curve after inverse Fourier transformation. It shows the positive blood pressure change (mmHg/h) for periods of blood pressure increase and the negative change during periods of blood pressure decrease.
- The red vertical lines mark the beginning and end (=duration) of the early-morning blood pressure increase and the time and extent of the maximum increase.
- The upper blood pressure limits (systolic, diastolic) are displayed as horizontal set point curves.

Note The blood pressure limits can be specified in the **Patient Information** tab in the **Blood pressure limits** section.

Displaying individual values

In the diagram, click the desired time. A vertical line appears and the measurement values are displayed in a window. To see adjacent measurement values, move the mouse over the diagram. The vertical line follows the movement of the mouse and the respective values are displayed.

Click again to deactivate the display.

Zooming into (enlarging) the diagram

Click onto the diagram and hold down the left mouse button and drag from the left to right to draw an enlargement section.

Zooming out (restore original size) of the diagram

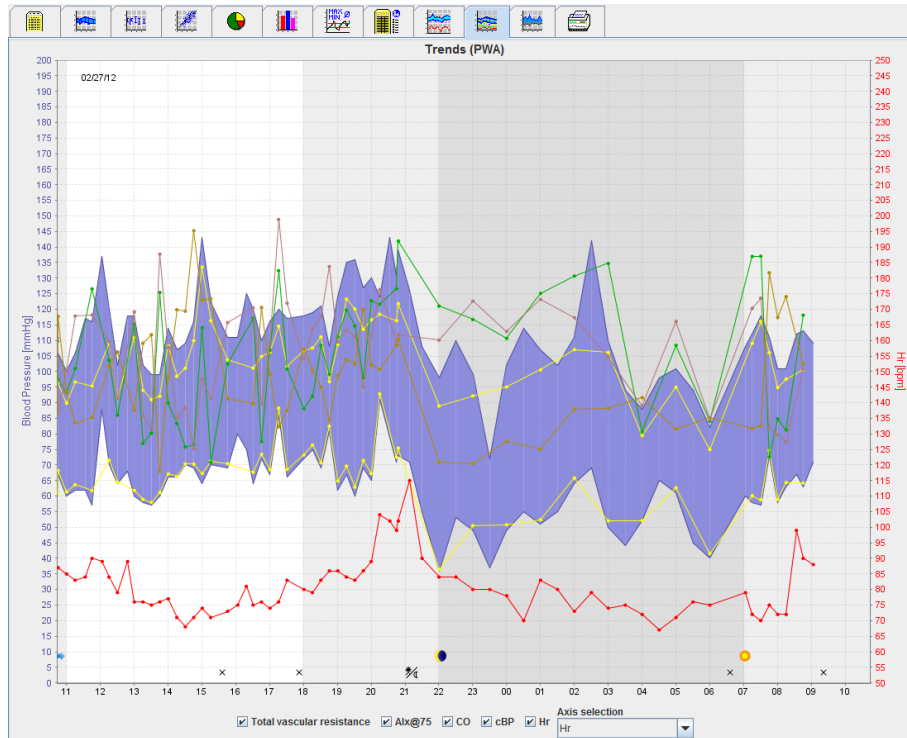
Click onto the diagram and hold down the left mouse button and drag from the right to left to restore back to the original size.


39 - Analyzing the measurement

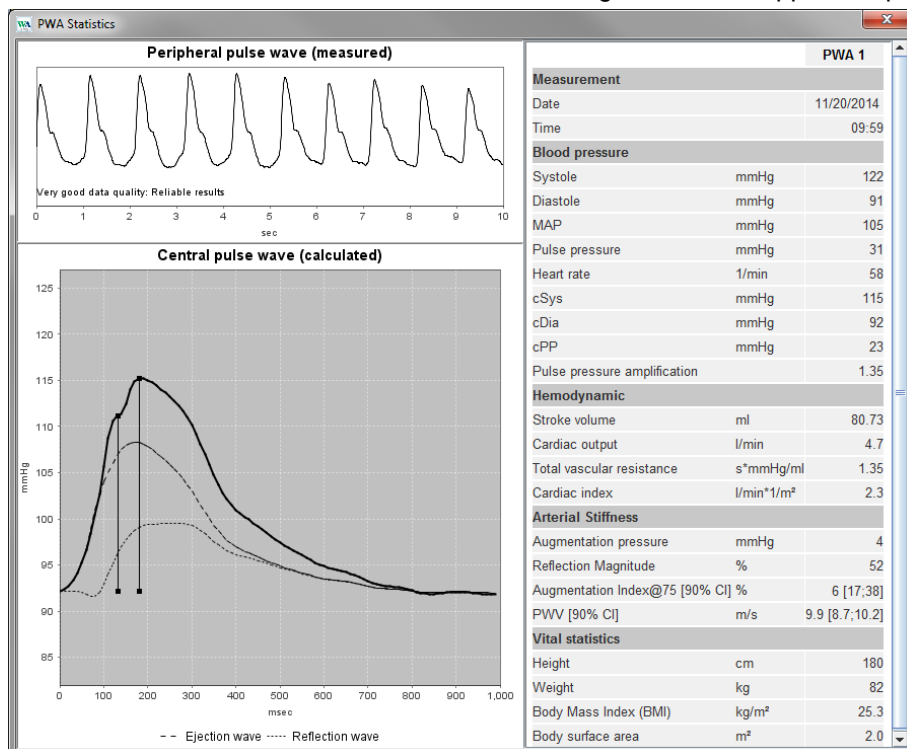
The Trends (PWA) tab

This analysis shows you the course of the PWA over 24 hours with a preset protocol 11. These following values are graphically displayed in a diagram as a function of time in the measurement series in addition to the blood pressure values and the pulse: Central blood pressure, Aix@75 [90% CI], Cardiac output [HmV], and Peripheral resistance.

1. To display the course of the above-mentioned values, click on the **Trends (PWA)** tab.



2. To display an individual PWA, click on the **Measurements**  tab.
3. Click to select a value in the table and the following window will appear displaying further details:

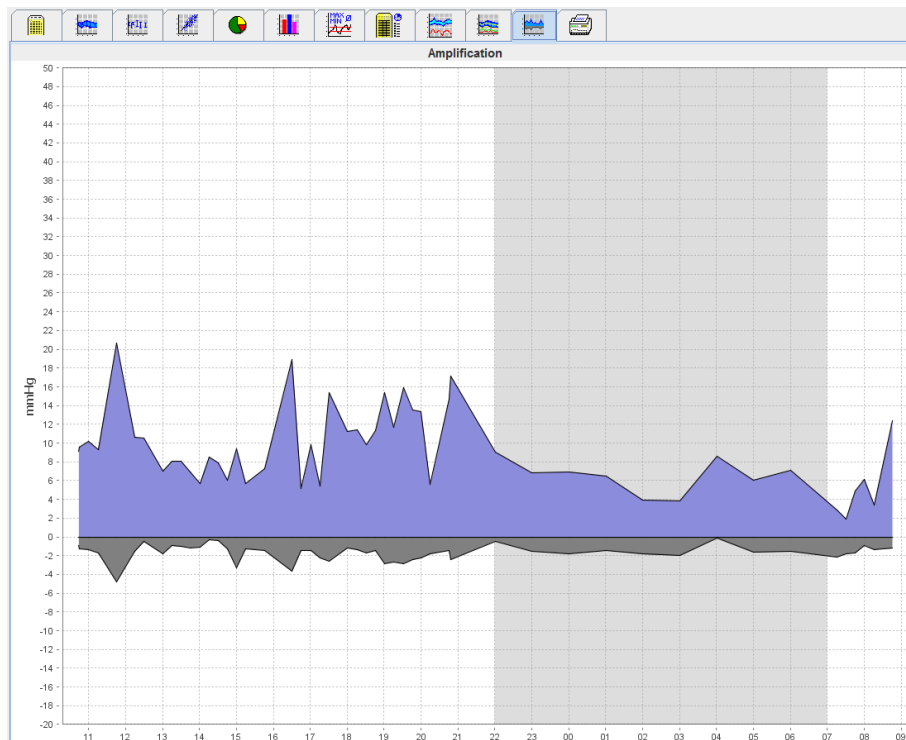


This displays the PWA in the same way as an individual PWA performed at the doctor's office.

40 - Analyzing the measurement

The Amplification tab

This analysis is used to monitor the variation of the difference between central and peripheral blood pressure values. The blue area indicates the difference between peripheral and central systolic values during the daytime and the grey area indicates the difference between peripheral and central diastolic values during the daytime.




The Print tab

The print function allows you to print out specific analyzes.

To print, click the **Print**  tab.

The figure shows the "Print" configuration window. It includes a "Print range" dropdown set to "24H". Below this are several checkboxes: "Patient information sheet" (unchecked), "Report" (checked), "Trends" (checked), "Bar chart" (checked), "Measurements" (checked), "Exceeding norms" (unchecked), "Rise and Fall" (unchecked), and "Frequency di..." (unchecked). There are also checkboxes for "Scatter Points" (unchecked) and "Hourly Intervals" (unchecked). On the right side, there is a "Customization" section with a "Printer" dropdown set to "WEM-DC\Canon LBP6670 UFR II_Einkauf". Below this are buttons for "Save", "Page format", "Print", and "Save as PDF".

Click the analyzes to be printed out.

Click . The **Print** window appears.

41 - Monitoring at the doctor's office

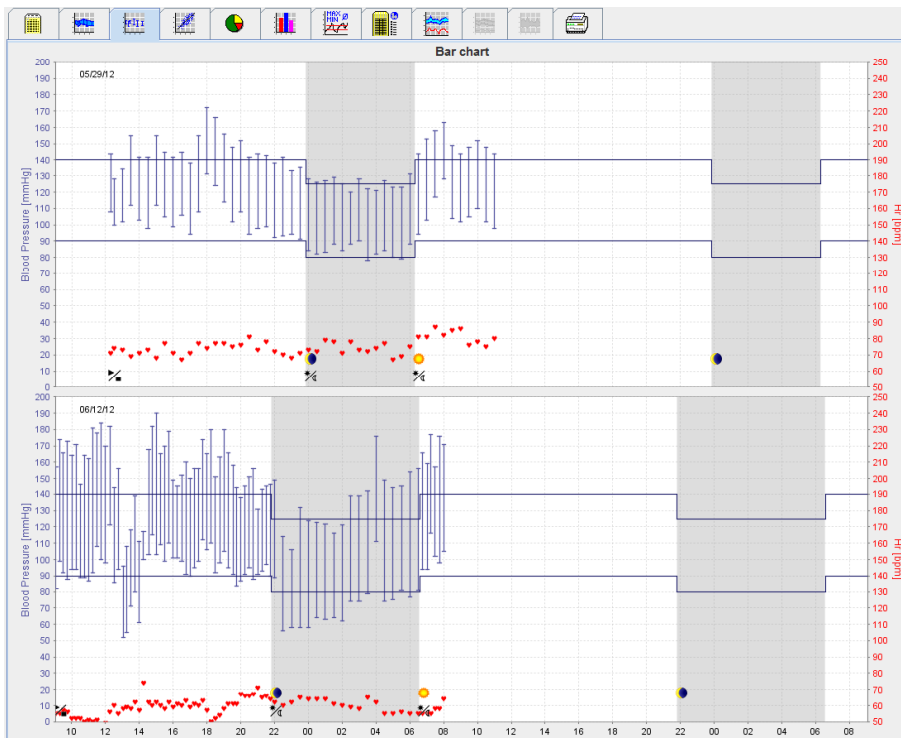
Comparing several measurement results

If more than one measurement results are saved under one patient, it is possible to compare these results. Depending on the analysis, diagrams of individual measurement results are displayed in a list or the values are accumulated and graphically displayed.

Selecting and comparing several measurement results

1. Click on the first measurement result to highlight the measurement.
2. Hold the “ctrl” (or “command”) key and click on other required measurement results to highlight them.
3. Click on the required analysis tab.

Example: Comparing the bar charts of two measurements



Monitoring at the doctor's office

The ABPM 7100 can be carried by the patient in the doctor's office, e.g. in the waiting room, and the measurement series is transferred directly via Bluetooth® to a computer at the doctor's office. Each measurement can be analyzed by the doctor immediately.

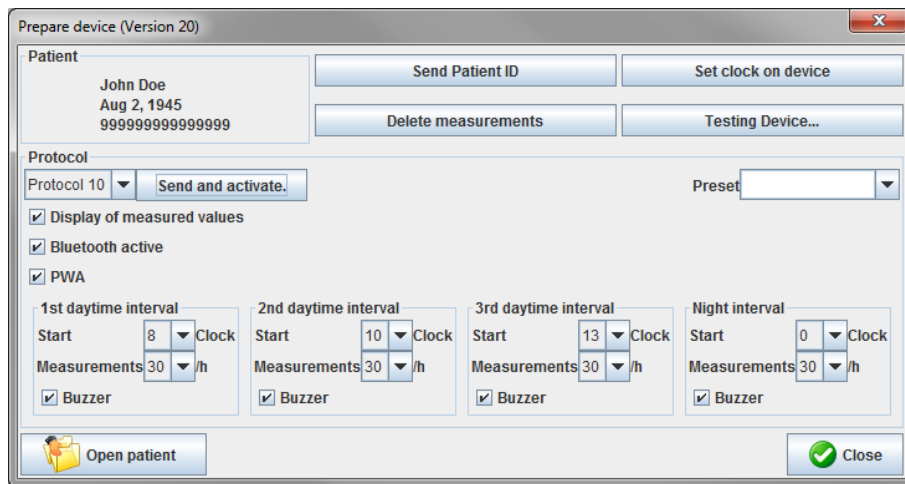
You can use the office monitoring to subject the patient to a narrow short-term control scan.

Attention The system does not claim to have alarm functions.

Preparing the ABPM 7100 for monitoring at the doctor's office

For office monitoring the Bluetooth® interface of the ABPM 7100 must be used.

42 - Monitoring at the doctor's office




The 'Prepare device (Version 20)' window is used for configuring the device. It contains the following sections:


- Patient:** Displays 'John Doe', 'Aug 2, 1945', and '999999999999999'. Buttons include 'Send Patient ID', 'Set clock on device', 'Delete measurements', and 'Testing Device...'. An 'Open patient' button is at the bottom left.
- Protocol:** A dropdown menu is set to 'Protocol 10'. A 'Send and activate.' button is next to it. A 'Preset' dropdown is on the right.
- Settings:** Checkboxes for 'Display of measured values', 'Bluetooth active', and 'PWA' are all checked.
- Intervals:** Four sections for '1st daytime interval', '2nd daytime interval', '3rd daytime interval', and 'Night interval'. Each has 'Start' (hour and clock) and 'Measurements' (per hour) settings. 'Buzzer' checkboxes are checked for each.
- Buttons:** 'Open patient' (bottom left) and 'Close' (bottom right, with a green checkmark).

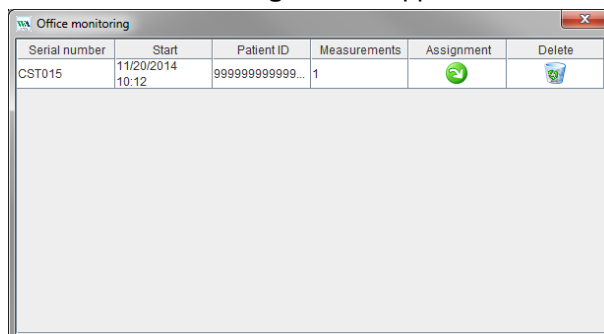
1. Select "Protocol 10" for office monitoring.
2. Select "Time Interval, 30, 20, 15, 12... measurements per hour".



Note For further information on the ABPM 7100 please refer to the directions for use of the ABPM 7100.

3. Attach the ABPM 7100 on the patient. Position the cuff and connect it to the ABPM 7100.
4. Tick "Bluetooth active".
5. To ensure that the ABPM 7100 works as required, press  to start a manual measurement. A successful measurement is required for protocol activation.
6. Wait for the first automatic measurement to be completed.

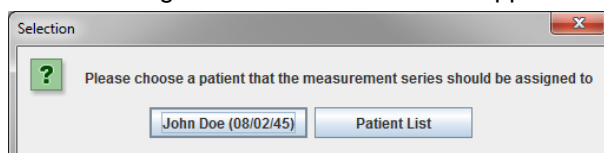
Assigning received measurement results

1. After the first measurement, the icon  will appear in the toolbar. Click on this icon.
2. The **Office Monitoring** window appears.



Serial number	Start	Patient ID	Measurements	Assignment	Delete
CST015	11/20/2014 10:12	999999999999999...	1		

3. Click on assign. The **Selection** window appears.



The 'Selection' window prompts the user to choose a patient for assignment. It contains a question mark icon, the text 'Please choose a patient that the measurement series should be assigned to', and two buttons: 'John Doe (08/02/45)' and 'Patient List'.

4. Here you can assign the measurement results to either the current open patient or to another patient from the patient list.

43 - Pulse Wave Analysis (PWA)

Pulse Wave Analysis (PWA)

Apart from the 24-hour blood pressure measurement, the HMS in connection with the ABPM 7100 also has an integrated pulse wave analysis system (PWA). This function can be unlocked with a valid PWA license key. Please consult Welch Allyn on device upgrading.

The pulse wave analysis is based on the concept that the arterial blood pressure curve contains haemodynamic information that exceeds peripherally measured blood pressure values. This is used to analyze all information on the central aortic pulse wave. The following values are emitted:

- Central blood pressure
- Central pulse pressure
- Augmentation pressure
- Augmentation Index
- Aix@75 [90% confidence interval]
- Cardiac output [HMF]
- Peripheral resistance
- Reflection coefficient
- Pulse Wave Velocity [PWV]

Performing PWA at the doctor's office

Pulse wave analysis is performed at the doctor's office via the Bluetooth® interface of the ABPM 7100.

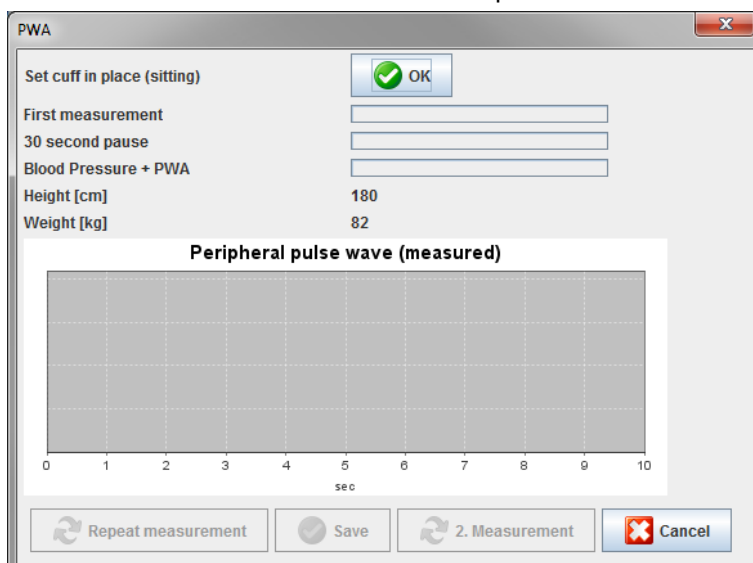
1. Position the cuff on the patient and connect the cuff to the ABPM 7100.
2. Switch on the ABPM 7100.
3. Select an existing patient or create a new patient in the **HMS**. By default, the PWA measurement is always assigned to the current patient on the screen.

Note The patient's age, height and weight must be entered into the **HMS** prior to perform PWA measurement.

4. Connect the ABPM 7100 to the **HMS** via Bluetooth®.



5. Then select **PWA Measurement** to call up the PWA measurement window.



44 - Pulse Wave Analysis (PWA)

- Click **OK** to start the measurement.
- Click **Save** once all measurement steps associated with PWA have been successfully completed.

Performing 24-hour PWA

In order to perform 24-hour PWA, the ABPM 7100 must be upgraded with a valid PWA license key and the HMS software version must either be 5.0 and above.

When preparing the ABPM 7100 to perform a 24-hour PWA measurement, select protocol 11.

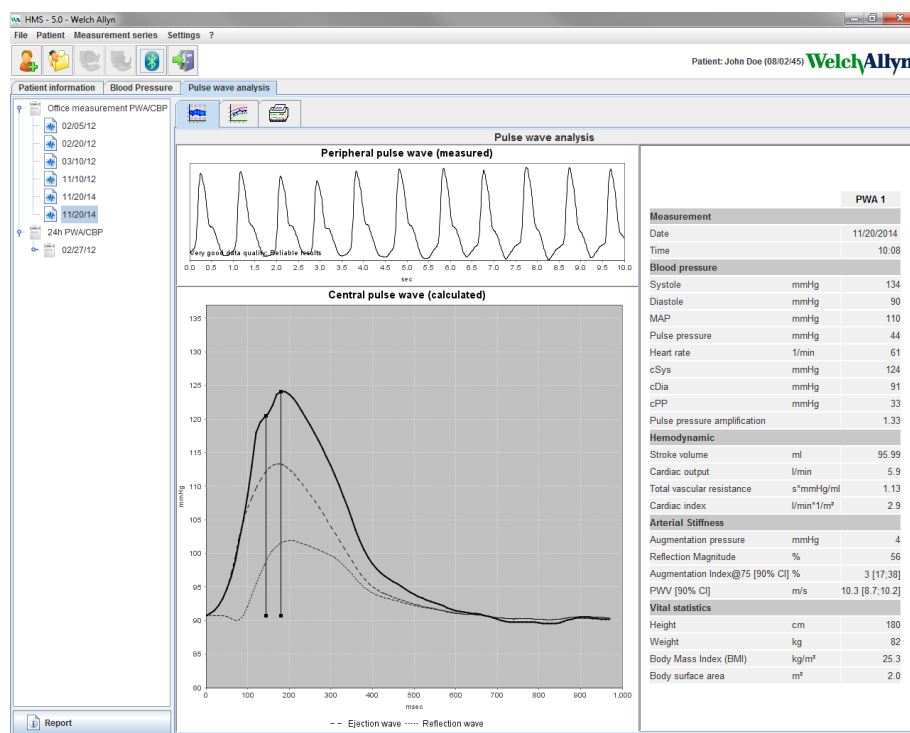
Once the ABPM 7100 is prepared with protocol 11, regular blood pressure measurement is performed at the preset intervals. After which, a PWA is additionally performed with the ABPM 7100 reinflates to record the pulses at diastolic pressure.

Transferring and analyzing 24-hour PWA measurement results

For transferring and analyzing of the 24-hour PWA measurement results perform the same steps as with the regular 24-hour ABPM.

Displaying the PWA

The following analysis appears automatically after a successful completed PWA:



From 10 pulse wave measurements, a filtered and average pulse wave is determined and in turn used to calculate the central aortic pulse wave.

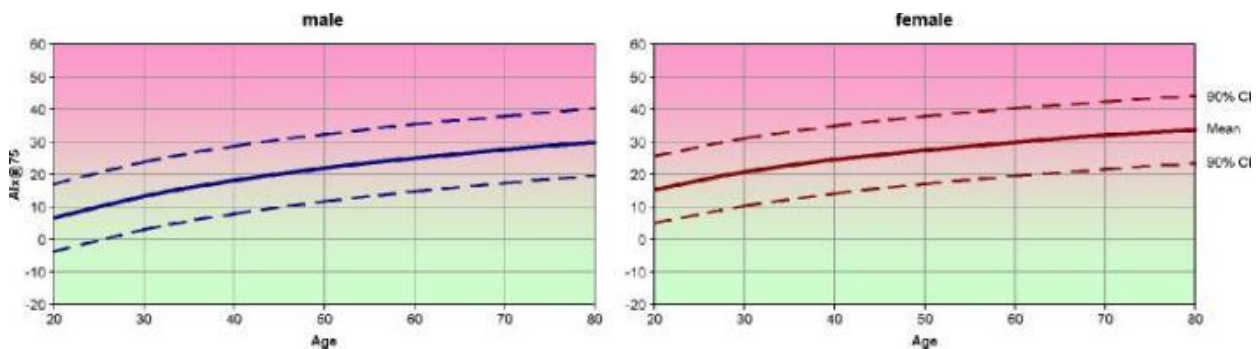
The Augmentation Index (Aix) is repeatedly cited in medical literature as dependent on gender, age and heart rate. This is why the use of a standardized display in accordance with these parameters is preferred. The Augmentation Index is initially normalized to a heart rate of 75 1/min with the help of an empirically determined regression¹.

This parameter is then known as Aix@75. If one were to examine a representative cross-section of the population as described in², the result would be an age-dependent estimate for the Aix@75, plus an associated confidence interval. These pertinent studies have also revealed a significant difference in the average Aix@75 between men and women.

Based on several internal researches with an independently ascertained cross-section of the population size of about 2000 people, the average values displayed below with 90% confidence intervals were determined.

45 - Changing the default settings of the HMS

As with the previously discussed case studies, the independently ascertained measurements revealed an increase in the Aix up to the age of 55 years. Both genders then reached a plateau. The difference in Aix levels between the genders is between 8% to 10%. If measurement values exceed the gender and age-specific interval, further examinations in accordance with the European Treatment Guidelines for Hypertension³ are recommended in order to determine the reasons of the disorder.



- [1] Wilkinson I.B. et al. Heart Rate Dependency of Pulse Pressure Amplification and Arterial Stiffness. American Journal of Hypertension 2002;15:24-30.
- [2] Fantin F. et al. Is augmentation index a good measure of vascular stiffness in the elderly? Age and Ageing 2007; 36: 43-48.
- [3] The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC). 2007 Guidelines for the management of arterial hypertension. European Heart Journal 2007; 28: 1462-1536.

Changing the default settings of the HMS

The following settings for the HMS can be specified:

- Analyzes:
 - Blood pressure limits
 - Basis of calculation
- User interface:
 - Language
 - Colors
 - Interfaces
 - Database
 - Bluetooth®

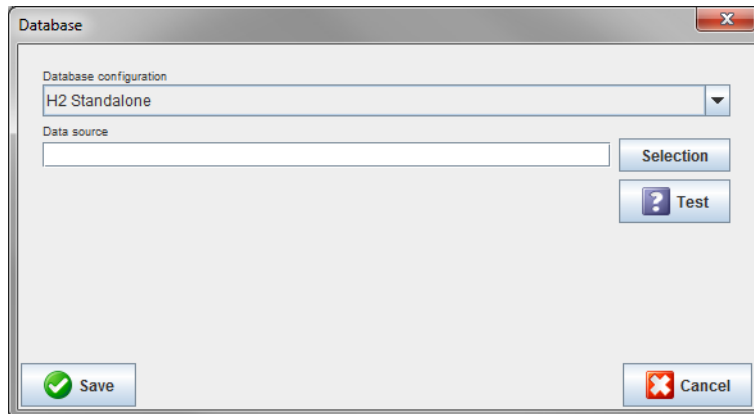
To change default settings of the **HMS**, click **Settings** in the menu bar and select the required function.

Database

Patient data and the associated measurement data are stored in a database. Here you can specify the information for access to the database. You can obtain further information from your Welch Allyn specialist.

46 - Changing the default settings of the HMS

1. In the menu bar, click **Settings** then **Database**. The **Database window** appears.

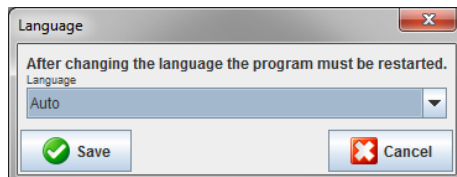


2. Enter the required information.
3. Click **Save**.

Changing the language

The user interface is available in various languages.

1. In the menu bar, click **Settings** then **Language** to display the **Language window**.



2. Select the required language from the drop-down field.
3. Once the modifications are completed, click **Save** to close the window.

Note For the new language to take effect, exit and restart the HMS.

Port settings

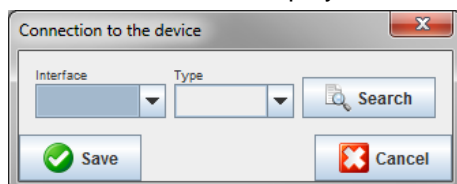
The interface to the following connections between the ABPM 7100 to the computer can be specified here:

- Cable with USB interface
- Bluetooth®

In the menu bar, click **Settings** then **Port settings** to display the **Port settings window**.

Specifying a serial / USB interface for the ABPM 7100

1. Click the **Serial / USB** tab.
2. Click **Add device** to display the **Connection to the device window**.



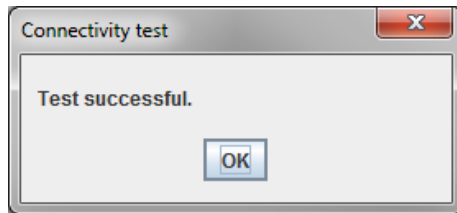
3. To search for a device, switch on the ABPM 7100.
4. Click **Search**. Detected devices will be displayed in the drop-down list. If no device is selected, a respective message will appear.

47 - Changing the default settings of the HMS

5. To add the device, click **Save**. The window disappears and the new device is displayed in the port settings list.

Performing a connectivity test for Serial / USB interface

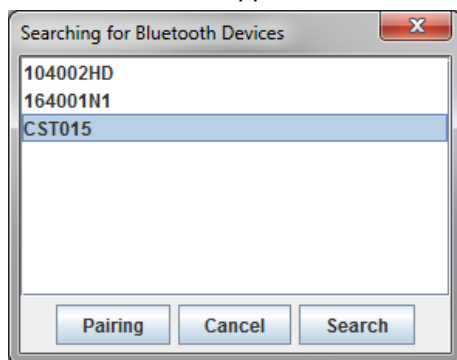
1. Click the interface of the ABPM 7100 you want to test.
2. Click **Connectivity test** and the following window appears with the result of the connectivity test.



If connection to the measurement device was not successful, a respective message will appear.

Specifying a Bluetooth® interface for the ABPM 7100

1. Click the **Bluetooth®** tab.
2. In the Bluetooth® tab, click **Add device**. The following instruction will appear: “Switch on the ABPM 7100 and change to pairing mode.”
3. Switch on the ABPM 7100 and change into **PAir** mode (refer to Connection via Bluetooth®).
4. Click **OK**. The **Searching for Bluetooth Devices** window appears and after a moment the device serial number will appear in the window.



5. Click to select the serial number.
6. Click **Pairing**. The following message appears: “Pairing successful.”
7. Click **OK**.
8. Click **Save**. The new device will be listed on the Interfaces window of the Bluetooth® tab.

Deleting the ABPM 7100 from the list

1. Click on the ABPM 7100 to be deleted.
2. Click **Delete device**.
3. Click **Ok** to confirm and the device serial number will be deleted from the list.

Saving the interface

To accept the modification, click on **Save** and the **Port settings** window closes.

Blood pressure limits

You can specify global limit values for systolic and diastolic blood pressure. If the limit values are exceeded, the measurement results will be marked accordingly in the analysis.

Note These values are automatically saved as limit values for newly created patients.

48 - Changing the default settings of the HMS

In general, the blood pressure limit values established by World Health Organization (WHO) do NOT APPLY for children and adolescents between the ages of 3 to 18 years. Current studies (Blood Pressure percentiles by Age and Height from Nonoverweight Children and Adolescents in Germany, Neuhauser et al.: Pediatrics accepted Dec 10 2010) have shown that the limits in children and adolescents are dependent on their age and gender.

In 2010, the European Society for Hypertension (ESH) published extensive tables (Management of high blood pressure in children and adolescents: recommendations of the European Society of Hypertension, Lurbe et al.: Journal of hypertension accepted Jun 9 2009) on which the HMS limit values are based on. The limit values are determined according to the 95% percentile curve.

The threshold is defined by the value which is equivalent or lower than 95% of a collective cohort (statistical evaluation for 15.000 children).

Any value exceeding this limit is indicated as hypertension.

To have the percentile curve displayed for children and adolescents between the ages of 3 to 18 years, the patient's date of birth must be entered, from which the **HMS** will calculate the patient's age.

Note By default, the **HMS** analysis will always refers to the current age of the patient. In order to maintain a patient history, a printout must be created for each appointment. The blood pressure limits for an individual patient can be specified on the **Patient Information** tab.

Note The blood pressure limits for an individual patient can be specified on the **Patient Information** tab.

Specifying blood pressure limit values for analysis

1. In the menu bar, click **Settings** then **Blood Pressure Limits** to display the following window:

Blood pressure limits

- Office measurements -

140 / 90 mmHg

- ABPM Values -

Average Values

Day 135 / 85 mmHg

Night 120 / 75 mmHg

Total 130 / 80 mmHg

Single Values

Day 140 / 90 mmHg

Night 125 / 80 mmHg

- Self measurements -

135 / 85 mmHg

- Dipping -

Inverted < 0 %

Non-Dipper < 10 %

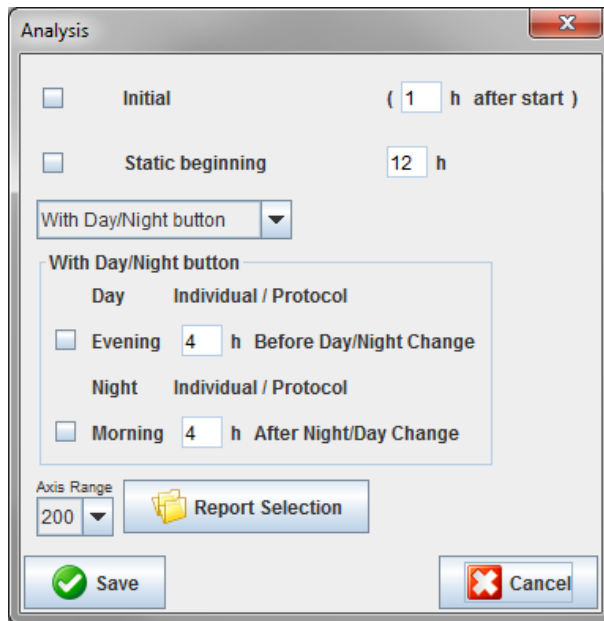
Normal < 20 %

2. Enter the limiting values.
3. To accept the new limit values, click **Save**.

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Analysis

In the menu bar, click **Settings** then **Analysis** to display the following window.

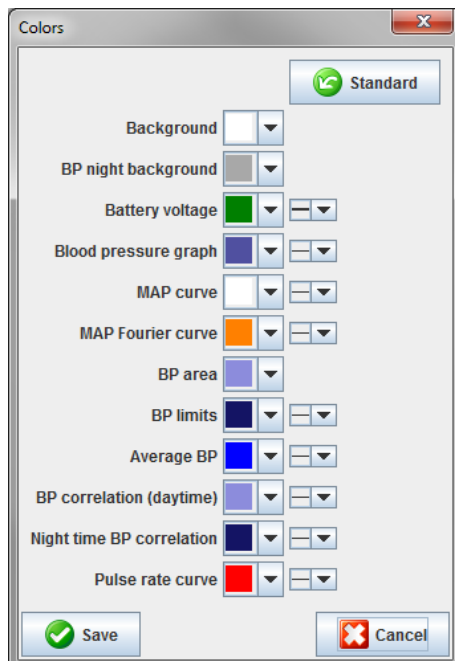


Various analysis settings can be selected:

- Initial: An additional start interval for the four daytime intervals.
- Static beginning: Start time of graphic displays.
- With or without Day / Night button: Settings for the start times of the four daytime intervals.
- Once the modifications are completed, click **Save** and the window closes.

Specifying colors for curves and diagram backgrounds

1. In the menu bar, click **Settings** then **Colors** to display the following window.



2. To change the colors, select the preferred color from the drop-down field.
3. Once the modifications are completed, click **Save** and the window closes.

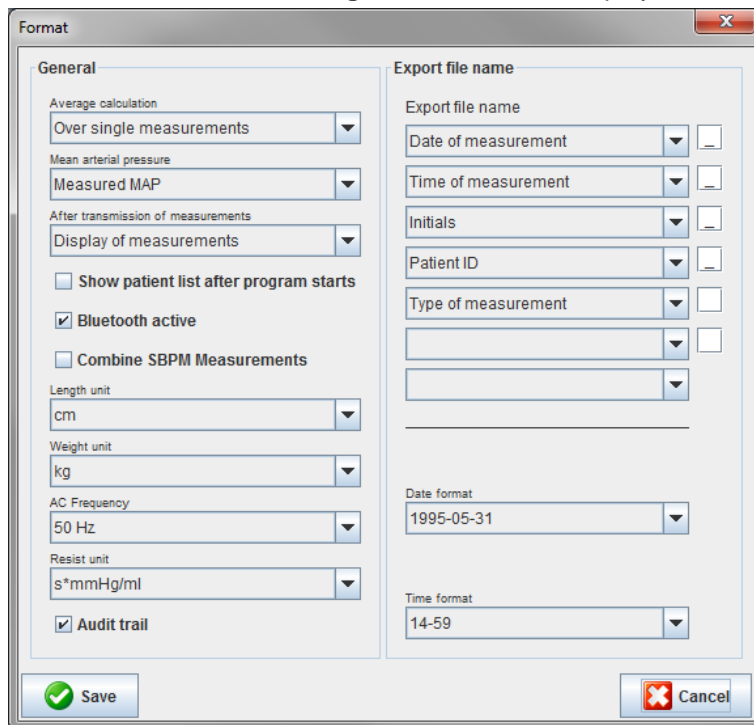
50 - Changing the default settings of the HMS

Format

Here you can specify standard procedures for:

- Average calculation (for all individual values or the hourly mean values, HM).
- Calculation of the mean arterial pressure (measured MAP or calculated MAP).
- The measurement value analysis to be displayed after the measurement data has been transmitted from the ABPM 7100 to the **HMS** (table of measurements or graphics).
- Whether the patient list or an “empty” application window is displayed after the program starts.
- Whether Bluetooth® is used.

1. In the menu bar, click **Settings** then **Format** to display the following window.



The 'Format' window is divided into two main sections: 'General' and 'Export file name'. The 'General' section includes dropdown menus for 'Average calculation' (set to 'Over single measurements'), 'Mean arterial pressure' (set to 'Measured MAP'), and 'After transmission of measurements' (set to 'Display of measurements'). It also features checkboxes for 'Show patient list after program starts' (unchecked), 'Bluetooth active' (checked), and 'Combine SBPM Measurements' (unchecked). Units are set to 'cm' for length and 'kg' for weight. 'AC Frequency' is set to '50 Hz' and 'Resist unit' is 's*mmHg/ml'. The 'Audit trail' checkbox is checked. The 'Export file name' section contains dropdown menus for 'Export file name' (set to 'Date of measurement'), 'Time of measurement', 'Initials', 'Patient ID', 'Type of measurement', and an empty dropdown. It also has 'Date format' (set to '1995-05-31') and 'Time format' (set to '14-59'). At the bottom are 'Save' and 'Cancel' buttons.

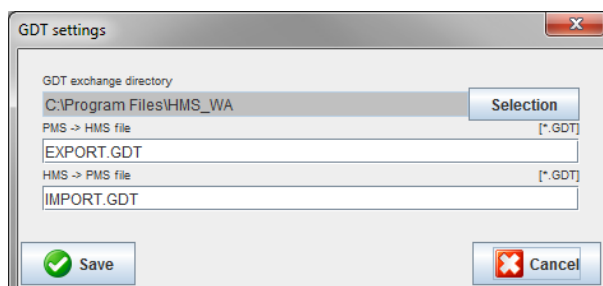
2. Specify the required settings.
3. Once the modifications are completed, click **Save** and the window closes.

GDT settings

Device Data Transfer (Gerätedatentransfer) is a data exchange format used by private-practices in the German healthcare system. The **GDT** interface serves system-independent data transmission purposes between medical measurement devices and an office IT.

The **GDT** settings are required for the automatic exchange of patient data between your office IT and **HMS**. If the settings are correct, the **HMS** can be started from your office software and patient data can be accepted directly.

In the menu bar, click on **Settings** then **GDT Settings**. The **GDT Settings** window appears.



The 'GDT settings' window shows the 'GDT exchange directory' set to 'C:\Program Files\HMS_WA'. It includes a 'Selection' button. Below are fields for 'PMS -> HMS file' (set to 'EXPORT.GDT') and 'HMS -> PMS file' (set to 'IMPORT.GDT'). At the bottom are 'Save' and 'Cancel' buttons.

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Click **Selection**. Here you can specify the joint directory of the **HMS** and your office IT. HMS and office IT must have the same directory settings. The **HMS** program directory should preferably be set first.

In the field **PMS -> HMS File**, enter the name of the GDT file, which transmits the patient data of your office IT to the HMS. The same name must be set in the HMS and in your office IT.

In the field **HMS -> PMS file**, enter the name of the GDT file, which transmits the report of the **HMS** to your office IT. The same name must be set in the **HMS** and in your office IT.

Enter the start file **HMS_GDT.exe** into the settings of your office IT.

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